

EXHIBIT 15

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control



Pharmacist's Manual

An Informational Outline of the
Controlled Substances Act

Revised 2010¹

¹ This manual replaces all previous editions of the Pharmacist's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

Drug Enforcement Administration
Pharmacist's Manual

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This manual has been prepared by the Drug Enforcement Administration, Office of Diversion Control, as a guide to assist pharmacists in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the pharmacy profession.

The 2010 edition replaces all previous editions of the Pharmacist's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

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SECTION I - INTRODUCTION

Disclaimer

This pharmacist's manual is intended to summarize and explain the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA), Title 21 United States Code (21 U.S.C.) 801-971 and the DEA regulations, Title 21, Code of Federal Regulations (21 C.F.R.), Parts 1300 to End. Pertinent citations to the law and regulations are included in this manual.

Printed copies of the complete regulations implementing the CSA (21 C.F.R. Part 1300 to End) may be obtained from:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

Both the C.F.R. and the Federal Register (which includes proposed and final rules implementing the CSA) are available on the internet through the U.S. Government Printing Office website. This website, which provides information by section, citation, and keywords, can be accessed at:

www.gpoaccess.gov

Unofficial copies of pertinent C.F.R. citations and this pharmacist's manual may be found on the internet at DEA's Diversion website (under "publications"):

www.DEAdviser.usdoj.gov

Should any pertinent provisions of the law or regulations be modified in the future, DEA will issue a revised electronic version of this document, which will be posted on the DEA Diversion website.

If you encounter errors in this document, please notify:

Drug Enforcement Administration
Attn: Liaison and Policy Section/ODL
8701 Morrisette Drive
Springfield, Virginia 22152

Inquiries regarding topics within this document may be addressed to your local DEA Diversion Field Office (Appendix K) or the address above.

Authorization for Public Dissemination

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Message from the Administrator

The Drug Enforcement Administration is pleased to provide you with the 2010 edition of the Pharmacist's Manual to assist you in understanding the provisions of the Controlled Substances Act (CSA) and its implementing regulations. This manual will answer questions you may encounter in the practice of pharmacy and provide guidance in complying with the CSA regulations. This edition has been updated to include information on the provisions of the Combat Methamphetamine Epidemic Act of 2005, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, and the Interim Final Rule entitled Electronic Prescriptions for Controlled Substances.

Your role in the proper dispensing of controlled substances is critical to the health of patients and helps protect society against drug abuse and diversion. Your adherence to the CSA, together with its objectives and your compliance, is a powerful resource for protecting the public health, assuring patient safety, and preventing the diversion of controlled substances and drug products containing listed chemicals.

Sincerely,



Michele M. Leonhart

Administrator

Drug Enforcement Administration

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Preface

The Drug Enforcement Administration (DEA) was established in 1973 to serve as the primary agency responsible for the enforcement of federal drug laws. The Controlled Substances Act (CSA) and its implementing regulations establish federal requirements regarding both illicit and licit controlled substances. With respect to pharmaceutical controlled substances, DEA's responsibility is twofold: to prevent diversion and abuse of these substances while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. In carrying out this mission, DEA works closely with state and local authorities and other federal agencies.

Under the framework of the CSA, all controlled substance transactions take place within a "closed system" of distribution established by Congress. Within this "closed system" all legitimate handlers of controlled substances - manufacturers, distributors, physicians, pharmacies, and others, must be registered with DEA (unless exempt) and maintain strict accounting for all controlled substance transactions.

To carry out this mission effectively, DEA seeks to educate its registrants regarding their legal obligations. It is DEA's goal to maintain a positive working relationship with all of its registrants, including pharmacies. DEA understands that it can best serve the public interest by working with the pharmacy community to prevent the diversion of pharmaceutical controlled substances and scheduled listed chemical products (SLCPs) into the illicit market.

Federal controlled substance laws are designed to function in tandem with state controlled substance laws. DEA works in cooperation with state professional licensing boards and state and local law enforcement officials to make certain that pharmaceutical controlled substances are prescribed, administered, and dispensed for a legitimate medical purpose in the usual course of professional practice. Within this framework, the majority of investigations into possible violations of controlled substance laws are carried out by state authorities. DEA focuses its investigations on cases involving violators of the highest level or most significant impact.

In the event a state board revokes the license of a pharmacy, DEA will request a voluntary surrender of the pharmacy's DEA registration. If the pharmacy refuses to surrender its registration, DEA will seek administrative action to revoke its DEA registration based on lack of state authorization. Additional administrative remedies that may be utilized to correct a lack of compliance include a letter of admonition or an administrative hearing. DEA may also pursue civil or criminal sanctions if there is sufficient evidence to justify a prosecution. All such actions are designed to protect the public health and safety.

In addition to the diversion of controlled substances, DEA is concerned with the diversion of certain chemicals used in the clandestine manufacture of controlled substances. Chemicals such as ephedrine and pseudoephedrine contained in over the counter and prescription substances are immediate precursors used in the illicit manufacture of methamphetamine and amphetamine. These products may be purchased or stolen from retail outlets, including pharmacies, for use in clandestine laboratories.

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Pharmacies that sell over the counter products containing ephedrine and pseudoephedrine must be "self-certified" as required by the Combat Methamphetamine Epidemic Act of 2005 (CMEA). The CMEA created a new category of products designated as SLCPs. SLCPs are products containing ephedrine, pseudoephedrine, or phenylpropanolamine that may be marketed or distributed lawfully in the United States as a non-prescription drug under the Food, Drug, and Cosmetic Act. The retail provisions of the CMEA went into effect on September 30, 2006 and require, among other things, employee training, self certification, placement of SLCPs out of customer reach, required identification, sales logbooks, sales and purchase limits, and others.

DEA and the pharmacy profession have strong common interests in the appropriate use of controlled substances and SLCPs. An effective working relationship to ensure compliance with CSA requirements will continue to produce lasting benefits on a national scale.

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SECTION II - SCHEDULES OF CONTROLLED SUBSTANCES

The drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. A listing of the substances and their schedules is found in the DEA regulations, 21 C.F.R. Sections 1308.11 through 1308.15. A controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence. Some examples of controlled substances in each schedule are outlined below.

NOTE: Drugs listed in schedule I have no currently accepted medical use in treatment in the United States and, therefore, may not be prescribed, administered, or dispensed for medical use. In contrast, drugs listed in schedules II-V have some accepted medical use and may be prescribed, administered, or dispensed for medical use.

Schedule I Controlled Substances

Substances in this schedule have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug or other substance under medical supervision.

Some examples of substances listed in schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("ecstasy").

Schedule II Controlled Substances

Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples of single entity schedule II narcotics include morphine and opium. Other schedule II narcotic substances and their common name brand products include: hydromorphone (Dilauidid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®), and fentanyl (Sublimaze® or Duragesic®).

Examples of schedule II stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Other schedule II substances include: cocaine, amobarbital, glutethimide, and pentobarbital.

Schedule III Controlled Substances

Substances in this schedule have a potential for abuse less than substances in schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples of schedule III narcotics include combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®) and products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with codeine®). Also included are buprenorphine products (Suboxone® and Subutex®) used to treat opioid addiction.

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Examples of schedule III non-narcotics include benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as oxandrolone (Oxandrin®).

Schedule IV Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances in schedule III.

An example of a schedule IV narcotic is propoxyphene (Darvon® and Darvocet-N 100®).

Other schedule IV substances include: alprazolam (Xanax®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Schedule V Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances listed in schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. These are generally used for antitussive, antidiarrheal, and analgesic purposes.

Examples include cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC® and Phenergan with Codeine®).

Scheduled Listed Chemical Product (SLCP)

An SLCP is defined as a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug.

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SECTION III - REGISTRATION REQUIREMENTS

New Pharmacy Registration

Every pharmacy that dispenses a controlled substance must be registered with the DEA. First, a state license must be obtained.

To register as a new pharmacy, the DEA Form 224 must be completed. The cost of the application fee is indicated on the application form. The certificate of registration must be maintained at the registered location and kept available for official inspection. If a person owns and operates more than one pharmacy, each place of business must be registered.

The DEA Form 224 should be completed online (www.DEAdiversion.usdoj.gov).

The screenshot shows the DEA website's main navigation bar with links for Home, About, Contact Us, and Log In. Below this, a sidebar on the left has links for Registration, Renewal, Transfer, and Cancellation. The main content area is titled "Office of Diversion Control" and "Registration Applications". It includes a sub-section for "Office of Diversion Control Web Interactive Forms (ODWF) NEW APPLICATIONS". It provides instructions for registration help via email to DEA.Registration.Help@usdoj.gov, noting to include the DEA Registration number in the email. A table lists "Legal Appointee Practices" such as Retail Pharmacies, Hospitals/Clinics, Practitioners, Teaching Institutions, or Non-Licensed Practitioner, Manufacturer, Distributor, Researcher, Medical Laboratories, Importer, Exporter, Narcotic Treatment Program, Domestic Clinicians. At the bottom, it specifies "MINIMUM ON-LINE REQUIREMENTS" and notes that the DEA Form 224 is for controlled substance registration and must be entered through the ODWF online application system, requiring a 128-bit encryption.

A paper version of the DEA Form 224 may be requested by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, Virginia 22152-2639

If a pharmacy needs a duplicate Certificate of Registration (DEA Form 223), a copy may be requested online via DEA's Diversion website, www.DEAdiversion.usdoj.gov, or contact DEA Headquarters at 1-800-882-9539 or via e-mail at DEA.Registration.Help@usdoj.gov.

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Renewal of Pharmacy Registration

A pharmacy registration must be renewed every three years utilizing DEA Form 224a, Renewal Application for DEA Registration. The cost of the application fee is indicated on the application form.

To renew a registration, the most current information from the pharmacy's existing registration must be utilized. A registrant can renew online no more than 60 days prior to the current expiration date. The DEA Form 224a should be completed online and can be found at www.DEAdviser.usdoj.gov.

| | |
|------------------------------------|--|
| Retail Pharmacies | Retail Pharmacies, Hospital/Clinic, Practitioner, Teaching Institution or High-Level Practitioner, Manufacturer, Distributor, Assessor/Analyst, Laboratory, Importer, Exporter, Domestic Chemicals, Abuse Deterrent Programs |
| Non-Prescription Pharmacies | |
| Controlled Substance Manufacturers | |
| Assessors/Analysts | |
| Laboratories | |
| Importers/Exporters | |
| Domestic Chemicals | |
| Abuse Deterrent Programs | |
| Obtain Receipts | This link may be used ONLY if you have previously submitted a Renewal Application through this tool and need an additional receipt. |
| Request Duplicate Certificate | Use this tool to request certificates for additional, misplaced, lost, or destroyed originals. |

MINIMUM ON-LINE REQUIREMENTS

The DEA Forms listed below are for those applying to DEA for a controlled substance registration. Data will be entered through a secure connection to the ODWIF online web application system. Your web browser must support 128-bit encryption.

You will need to have the following information handy in order to complete the forms:

- Tax ID number and/or Federal Security Number
- State Controlled Substance Registration Information
- State Medical License information
- Credit Card (Visa, MasterCard, Discover or American Express)

The ODWIF system can only process credit card transactions at this time. If you are paying by check, you will need to use the PDF version of the form, then print and mail the form to the address listed on the form.

If the registrant has not renewed online approximately 50 days before the registration expiration date, a renewal application is sent to the registrant at the mailing address listed on the current registration. If the renewal form is not received by the 30th day before the expiration date of the current registration, the pharmacy should contact the local DEA Registration Specialist (Appendix J) or DEA Headquarters at 1-800-882-9539 and request a renewal registration form.

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NOTE: Once the expiration date has passed and no renewal has been received by DEA, the pharmacy has no authority to handle controlled substances.

Affidavit for Renewal of Retail Chain Pharmacy Registration

Corporations that own or operate a chain of pharmacies may submit a single DEA Form 224b, Retail Pharmacy Registration Affidavit for Chain Renewal. This affidavit, along with a list of the corporation's registrations, is provided in lieu of a separate registration application for each pharmacy registration. No registration may be issued unless the completed affidavit is received by DEA. The corporation should retain a copy of this affidavit with their readily retrievable records for the duration of the registrations covered by the affidavit. A responsible individual must answer the questions listed on the affidavit on behalf of the corporation as they pertain to each registrant. The original affidavit along with the registration application fee and the list of registrations should be mailed to:

Registration Chain Renewal
Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, Virginia 22152-2639

Change of Business Address

A pharmacy that moves to a new physical location must request a modification of registration. Modifications are handled in the same manner as applications and must be approved by DEA. A modification of registration can be requested online at www.DEAdiversion.usdoj.gov or in writing to the local DEA Registration Specialist (Appendix J) responsible for the area in which the pharmacy is located. If the change of address involves a change in state, the proper state issued license and, if applicable, controlled substances registration must be obtained prior to the approval of modification of the federal registration. If the modification is approved, DEA will issue a new certificate of registration and, if requested, new schedule II order forms (DEA Form 222). The registrant should maintain the new certificate with the old certificate until expiration. A Renewal Application for Registration (DEA Form 224a) will only be sent to the mailing address on file with DEA. It will not be forwarded.

Termination of Registration

A pharmacy that discontinues business activities either completely or only regarding controlled substances must return its DEA registration certificate and unused official order forms (DEA Form 222) to the local DEA Registration Specialist (Appendix J). In addition, DEA may ask for the location of where inventories, prescriptions, and other required controlled substance records will be stored during the requisite two-year retention period.

Unwanted controlled substances in the pharmacy's possession must be disposed of in accordance with DEA regulations (see Section IV, *Transfer or Disposal of Controlled Substances*).

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Transfer of Business

A pharmacy registrant that transfers its business operations to another pharmacy registrant must submit in person or by registered or certified mail, return receipt requested, to the Special Agent in Charge in his/her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information:

1. The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);
2. The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);
3. Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed); and
4. The date on which the transfer of controlled substances will occur.

On the day the controlled substances are transferred, a complete inventory must be taken and a copy of the inventory must be included in the records of both the person transferring the business and the person acquiring the business. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. It is not necessary to send a copy of the inventory to the DEA unless requested by the Special Agent in Charge.

To transfer schedule II controlled substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

All controlled substance records required to be kept by the registrant-transferor shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

If the registrant acquiring the pharmacy owns at least one other pharmacy licensed in the same state as the pharmacy being transferred, the registrant may apply for a new DEA registration prior to the date of transfer. DEA will issue a registration which will authorize the registrant to obtain controlled substances at the time of transfer, but the registrant may not dispense controlled substances until the pharmacy has been issued a valid state pharmacy license.

A DEA registration application to transfer ownership of an existing pharmacy can be facilitated if the applicant includes an affidavit verifying that the pharmacy has been registered by the state licensing agency. The affidavit verifying the existence of the state license should be attached to the initial application for registration.

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Denial, Suspension, or Revocation of Registration

Under the CSA (21 U.S.C. § 824 (a)), DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the registrant:

1. Has materially falsified the application;
2. Has been convicted of a felony relating to a controlled substance or a List I chemical;
3. Had a State license or registration suspended, revoked, or denied by a competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or List I chemicals or has had the suspension, revocation, or denial of a registration recommended by competent State authority;
4. Has committed an act which would render the DEA registration inconsistent with the public interest; or
5. Has been excluded (or directed to be excluded) from participation in a program pursuant to Title 42 U.S.C. § 1320a-7(a), that is, a Medicaid or Medicare program.

Denial of Registration in the Public Interest

In determining the public interest, the CSA states the following factors are to be considered (21 U.S.C. § 823 (f)):

1. The recommendation of the appropriate State licensing board or professional disciplinary authority.
2. The applicant's experience in dispensing or conducting research with respect to controlled substances.
3. The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.
4. Compliance with applicable State, Federal, or local laws relating to controlled substances.
5. Such other conduct which may threaten the public health and safety.

Chemical Registration Requirements

Registration is not required for regulated sellers of SLCPs. However, a regulated seller must self-certify with DEA pursuant to federal law (see Section XIV, *Self-Certification*). A regulated seller is defined as a grocery store, general merchandise store, drug store, or other entity engaged in over-the-counter sales of ephedrine (both single-entity and combination products), pseudoephedrine, or phenylpropanolamine products, directly to walk-in customers or in face-to-face transactions by direct sales. A mobile retail vendor is defined as a person or entity that makes sales at retail from a stand that is intended to be temporary or is capable of being moved from one location to another.

Federal law requires any person who is engaged in the wholesale distribution of an SLCP to obtain a registration as a chemical distributor. A distributor who does not meet all the requirements for a regulated seller of SLCPs, or who does not meet the requirements for distributors required to submit "mail-order" reports, is a wholesale distributor.

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Note: this would include those pharmacies that sell quantities of SLCPs to institutions, including long term care facilities, jails, and other institutional-type settings for non-patient specific use. Such pharmacies are often referred to as "closed door" pharmacies.

Retail pharmacies that are registered to handle controlled substances need not obtain a separate DEA chemical registration for retail distribution of SLCPs. If a pharmacy desires to engage in the wholesale distribution of bulk quantities of SLCPs, the pharmacy is required to register with DEA as a chemical distributor because these activities fall outside the definition of a regulated seller. Therefore, the pharmacy would be subject to the registration requirements that apply to wholesale distributors for those distribution activities, and subject to the pharmacy requirements for its pharmacy activities. To obtain a DEA chemical distributor registration, a pharmacy may complete the DEA Form 510 online at www.DEAdversion.usdoj.gov. A paper version may be requested by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, Virginia 22152-2639

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SECTION IV - TRANSFER OR DISPOSAL OF CONTROLLED SUBSTANCES

Transfer of Controlled Substances

A pharmacy may hire an outside firm to inventory, package, and arrange for the transfer of its controlled substances to another pharmacy, the original supplier, or the original manufacturer. The pharmacy is responsible for the actual transfer of the controlled substances and for the accuracy of the inventory and records. The records involving the transfer of controlled substances must be kept readily available by the pharmacy for two years for inspection by the DEA.

To transfer schedule II substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

Transfer to a Pharmacy

If a pharmacy goes out of business or is acquired by a new pharmacy, it may transfer the controlled substances to another pharmacy. On the day the controlled substances are transferred, a complete inventory must be taken which documents the drug name, dosage form, strength, quantity, and date transferred. In addition, DEA Form 222 or the electronic equivalent must be prepared to document the transfer of schedule II controlled substances. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. A copy of the inventory must be included in the records of each pharmacy. It is not necessary to send a copy of the inventory to the DEA. The pharmacy acquiring the controlled substances must maintain all records involved in the transfer of the controlled substances for two years.

Transfer to the Original Supplier or Original Manufacturer

Any pharmacy may transfer controlled substances to the original supplier or the original manufacturer that is appropriately registered with the DEA. The pharmacist must maintain a written record showing:

1. The date of the transaction.
2. The name, strength, dosage form, and quantity of the controlled substance.
3. The supplier or manufacturer's name, address, and registration number.

The DEA Form 222 or the electronic equivalent will be the official record for the transfer of schedule II controlled substances.

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Disposal of Controlled Substances

A pharmacy may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. The pharmacy should contact the local DEA Diversion Field Office (Appendix K) for an updated list of DEA registered reverse distributors. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA. The DEA procedures established for the disposal of controlled substances must not be construed as altering in any way the state laws or regulations for the disposal of controlled substances.

Reverse Distributors Authorized to Dispose Controlled Substances

A pharmacy may forward controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. When a pharmacy transfers schedule II controlled substances to a reverse distributor for destruction, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the pharmacy. When schedules III-V controlled substances are transferred to a reverse distributor for destruction, the pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred. The DEA registered reverse distributor who will destroy the controlled substances is responsible for submitting a DEA Form 41 (Registrants Inventory of Drugs Surrendered) to the DEA when the controlled substances have been destroyed. A DEA Form 41 should **not** be used to record the transfer of controlled substances between the pharmacy and the reverse distributor disposing of the drugs.

A paper version of the DEA Form 41 may be requested by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, Virginia 22152-2639

Disposal of Controlled Substances by Persons Not Registered with DEA

On January 21, 2009, DEA published in the Federal Register an Advance Notice of Proposed Rulemaking (ANPRM), *Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration*. This ANPRM sought comments on how to address the issue of disposal of dispensed controlled substances held by DEA nonregistrants (i.e., ultimate users, long term care facilities). DEA was interested in the possible options that would enable nonregistrants to dispose of unwanted controlled substances, while also protecting public health and public safety, and minimizing the possibility of diversion. The public comment period for this ANPRM ended on March 23, 2009.

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SECTION V - SECURITY REQUIREMENTS

Requests for Employment Waivers for Certain Pharmacy Employees

Under 21 C.F.R. § 1301.76(a), a registrant must not employ in a position which allows access to controlled substances any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for DEA registration denied, revoked, or surrendered for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

However, 21 C.F.R. § 1307.03 does permit registrants desiring to employ an individual who meets this definition to request an exception to this requirement. The employer must have a waiver approved before allowing such an employee or prospective employee to have access to controlled substances. A waiver request should be sent by the employer to the following address:

Drug Enforcement Administration
Attn: Regulatory Section/ODG
8701 Morrissette Drive
Springfield, Virginia 22152

A registrant that applies for such a waiver should understand that the following factors will be considered by the DEA in the approval process and should provide details relevant to each factor as part of the waiver request submitted, since a waiver will not be considered unless there are valid reasons to believe that diversion is unlikely to occur:

1. A detailed description of the nature and extent of the individual's past controlled substances violations, including all pertinent documentation;
2. Current status of the individual's state licensure;
3. Extent of individual's proposed access to controlled substances. "Access" is not limited to only physical access to controlled substances, but includes any influence over the handling of controlled substances;
4. Registrant's proposed physical and professional safeguards to prevent diversion by the individual;
5. Status of employing registrant regarding handling of controlled substances;
6. Other pertinent information uncovered by DEA in its investigation of the individual's or registrant's handling of controlled substances; and
7. All other relevant factors or materials.

Controlled Substance Theft or Significant Loss

Should a theft or significant loss of any controlled substance occur at a pharmacy, the following procedures must be implemented within one business day of the discovery of the theft or loss.

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A. Notify DEA and Local Police

The theft of controlled substances from a registrant is a criminal act and a source of diversion that requires notification to DEA. A pharmacy must notify in writing the local DEA Diversion Field Office (Appendix K) within one business day of discovery of a theft or significant loss of a controlled substance. Although not specifically required by federal law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. Prompt notification to enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion. If there is a question as to whether a theft has occurred or a loss is significant, a registrant should err on the side of caution and report it to DEA and local law enforcement authorities.

DEA must be notified directly. This requirement is not satisfied by reporting the theft or significant loss in any other manner. For example, a corporation which owns or operates multiple registered sites and wishes to channel all notifications through corporate management or any other internal department responsible for security, must still provide notice directly to DEA in writing within one business day upon discovery and keep a copy of that notice for its records. The notice must be signed by an authorized individual of the registrant.

B. Complete DEA Form 106

A pharmacy must also complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances) which can be found online at www.DEAdiversion.usdoj.gov under the Quick Links section. The DEA Form 106 is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved. A paper version of the form can be obtained by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
8701 Morrissette Drive
Springfield, Virginia 22152

If completing the paper version, the pharmacy should send the original DEA Form 106 to the local DEA Diversion Field Office (Appendix K) and keep a copy for its records. Please see the *Guidelines for Completing the DEA Form 106* (Appendix I) for additional guidance.

The DEA Form 106 must include the following information:

1. Name and address of the firm (pharmacy),
2. DEA registration number,
3. Date of theft or loss (or when discovered if not known),
4. Name and telephone number of local police department (if notified),
5. Type of theft (e.g., night break-in, armed robbery),
6. List of identifying marks, symbols, or price codes (if any) used by the pharmacy on the labels of the containers, and
7. A listing of controlled substances missing, including the strength, dosage form, and size of container (in milliliters if liquid form) or corresponding National Drug Code numbers.

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C. If Investigation Finds No Theft or Loss

If, after the initial notification to DEA, the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, a DEA Form 106 does not need to be filed. However, the registrant must notify DEA in writing of this fact in order to resolve the initial report and explain why no DEA Form 106 was filed regarding the incident.

D. Registrant's Responsibility for Identifying "Significant Loss"

Although the CSA regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. Whether a "significant loss" has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer.

Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

When determining whether a loss is significant, a registrant should consider, among others, the following factors:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances;
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known
5. Whether the specific controlled substances are likely candidates for diversion; and
6. Local trends and other indicators of the diversion potential of the missing controlled substances.

If it is determined that the loss is not significant, the registrant should place a record of the occurrence in a theft and loss file for future reference. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management's discretion.

In-Transit Loss

When all or part of an in-transit shipment of controlled substances fails to reach its intended destination, the supplier is responsible for reporting the in-transit loss of controlled substances to DEA. The purchaser is responsible for reporting any loss of controlled substances after he/she has signed for or taken custody of a shipment. If it is discovered after that point that an in-transit loss or theft has occurred; the purchaser must then submit a DEA Form 106. If the purchaser does not take custody of the shipment and instead returns it to the supplier, it is the supplier's responsibility for reporting any loss of controlled substances in the original shipment.

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In-Transit Loss from Central Fill Pharmacy

Central fill pharmacies must comply with 21 C.F.R. § 1301.74(e) when selecting private, common or contract carriers to transport filled prescriptions to a retail pharmacy for delivery to an ultimate user. Pursuant to 21 C.F.R. § 1301.76(d), when a central fill pharmacy contracts with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting the in-transit loss upon discovery of such loss by use of a DEA Form 106. In addition, when a retail pharmacy contracts with private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery using a DEA Form 106.

Breakage and Spillage

The breakage or spillage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, or spillage or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. When this disposal occurs, it must be reported to DEA on a DEA Form 41 (Registrants Inventory of Drugs Surrendered). Damaged goods may also be disposed of through shipment to a reverse distributor or by a DEA approved process as defined in Section IV, *Transfer or Disposal of Controlled Substances*.

A paper version of the DEA Form 41 may be requested by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
8701 Morrisette Drive
Springfield, Virginia 22152

Robberies and Burglaries Involving Controlled Substances

The Controlled Substance Registrant Protection Act of 1984 (CSRPA) was enacted to protect DEA registrants against certain crimes (see Title 18 U.S.C. § 2118 for a complete text of CSRPA). The CSRPA provides for the federal investigation of controlled substances thefts and robberies if any of the following conditions are met:

1. The replacement cost of the controlled substances taken is \$500 or more.
2. Interstate or foreign commerce was involved in the execution of the crime.
3. A person was killed or suffered significant bodily injury as a result of the crime.

Penalties Upon Conviction - The perpetrator(s) convicted of violating CSRPA's provisions may be subject to the following penalties:

1. Burglary or robbery - a maximum \$25,000 fine and/or 20 years imprisonment.
2. If a dangerous weapon was used to carry out the crime - a maximum \$35,000 fine and/or 25 years imprisonment.
3. If death resulted from the crime - a maximum \$50,000 fine and/or life imprisonment.

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SECTION VI - RECORDKEEPING REQUIREMENTS

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

All required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials. Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant. All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records. Recordkeeping requirements for prescriptions are detailed in Section VI, *Prescription Records*.

Readily retrievable is defined as:

1. Records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or
2. Records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Required Records

The records which must be maintained by a pharmacy are:

1. Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
2. Power of Attorney authorization to sign order forms
3. Receipts and/or invoices for schedules III, IV, and V controlled substances
4. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
5. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
6. Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
7. Reports of Theft or Significant Loss (DEA Form 106), if applicable
8. Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
9. Records of transfers of controlled substances between pharmacies
10. DEA registration certificate
11. Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005

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Central Recordkeeping

A registrant desiring to maintain shipping and financial records (but not executed official order forms) at a central location rather than the registered location must submit written notification of his/her intention by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the local DEA Diversion Field Office in which the registrant is located (Appendix K). Unless the registrant is informed by the DEA that the permission to keep central records is denied, the registrant may begin maintaining central records 14 days after DEA receives this notification. Central recordkeeping requirements are described in 21 C.F.R. § 1304.04. Central recordkeeping permits are no longer issued by the DEA.

Prescription Records

Pharmacies have two options for filing paper prescription records and one option for electronic prescription records. If there is a conflict between federal and state requirements for filing prescriptions, DEA recognizes that the pharmacy must choose a filing system that would comply with both federal and state law. All prescription records must be *readily retrievable* for DEA inspection. Controlled substance prescriptions must be filed in one of the following ways:

Paper Prescriptions Records Option 1 (Three separate files):

1. A file for schedule II controlled substances dispensed.
2. A file for schedules III, IV and V controlled substances dispensed.
3. A file for all noncontrolled drugs dispensed.

Paper Prescriptions Records Option 2 (Two separate files):

1. A file for all schedule II controlled substances dispensed.
2. A file for all other drugs dispensed (noncontrolled and those in schedules III, IV and V). If this method is used, a prescription for a schedule III, IV or V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high. If a pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy with a red "C" is waived.

Electronic Prescription Records

1. If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.
2. Electronic records must be maintained electronically for two years from the date of their creation or receipt. However, this record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to pharmacists or pharmacies.
3. Records regarding controlled substances must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.

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Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of 21 C.F.R. §1311. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the DEA or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

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SECTION VII - INVENTORY REQUIREMENTS

An "inventory" is a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for schedule II controlled substances and an estimated count or measure of the contents of a schedule III, IV, or V controlled substance (unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents must be made). The CSA also requires that all inventory records be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection. In addition, the inventory records of schedule II controlled substances must be kept separate from all other controlled substances.

Initial Inventory

When issued a DEA registration, a registrant must take an initial inventory, which is an actual physical count of all controlled substances in their possession. If there are no stocks of controlled substances on hand, the registrant should make a record showing a zero inventory. There is no requirement to submit a copy of the inventory to the DEA. The C.F.R. requires that the inventory include:

1. The date of the inventory,
2. Whether the inventory was taken at the beginning or close of business,
3. The name of each controlled substance inventoried,
4. The finished form of each of the substances (e.g., 10 milligram tablet),
5. The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle),
6. The number of commercial containers of each finished form (e.g., four 100 tablet bottles), and
7. A count of the substance - if the substance is listed in schedule II, an exact count or measure of the contents or if the substance is listed in schedules III, IV, or V, an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case, an exact count of the contents is required.

DEA recommends, but does not require, an inventory record include the name, address, and DEA registration number of the registrant, and the signature of the person or persons responsible for taking the inventory.

Biennial Inventory

Following the initial inventory, the registrant is required to take a biennial inventory (every two years), which requires the same information as the initial inventory (see list above) of all controlled substances on hand. The biennial inventory may be taken on any date which is within two years of the previous inventory date. There is no requirement to submit a copy of the inventory to DEA.

Newly Scheduled Controlled Substance Inventory

When a drug not previously listed as a controlled substance is scheduled or a drug is rescheduled, the drug must be inventoried as of the effective date of scheduling or change in scheduling.

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SECTION VIII - ORDERING CONTROLLED SUBSTANCES

Ordering Schedule II Controlled Substances

Only schedules I and II controlled substances are ordered with an official order form, DEA Form 222, or the electronic equivalent (see below, *Controlled Substance Ordering System (CSOS) - Electronic Order Forms*). A DEA Form 222 is required for each distribution, purchase, or transfer of a schedule II controlled substance.

When a controlled substance has been moved by DEA from schedule II to another schedule at the federal level, in many states it may remain a schedule II controlled substance pending any legislative or administrative action that may result from the federal action. Many states require transactions that involve substances they classify as schedule II be made via official order forms (DEA Form 222) or the electronic equivalent. When federal law or regulations differ from state law or regulations, a pharmacy is required to abide by the more stringent aspects of both the federal and state requirements. When the use of DEA Form 222 or the electronic equivalent for the transfer of a controlled substance is not required under federal law, its use as mandated by these states does not violate federal law and is therefore permitted.

Requesting Official Order Forms

The unexecuted DEA Form 222 can be requested initially by checking "block 3" on the application for a new registration (DEA Form 224). The DEA Form 224 can be found online at www.DEAdversion.usdoj.gov.

Once a registrant has received a DEA registration number, additional DEA Forms 222 may be ordered online at www.DEAdversion.usdoj.gov. When requesting additional DEA Forms 222 online, a valid DEA registration number, business name, and contact telephone number are required. The registrant may also request DEA Forms 222 by calling the DEA Headquarters Registration Section at 1-800-882-9539 or by contacting the local DEA Registration Specialist (Appendix J).

Each book of DEA Form 222 consists of seven sets of forms. Each pharmacy is provided a maximum of six books at one time unless its needs exceed this limit. In such a case, the pharmacy should contact the local DEA Registration Specialist (Appendix J) to request additional books.

Completing Official Order Forms

When ordering schedule II controlled substances, the purchaser is responsible for filling in the number of packages, the size of the package, and the name of the item. Each DEA Form 222 must be signed and dated by a person authorized to sign a registration application or a person granted power of attorney (see below, *Power of Attorney to Sign an Official Order Form*). When the items are received, the pharmacist must document on the purchaser's copy (copy three) the actual number of packages received and the date received.

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The executed DEA Form 222 must be maintained separately from the pharmacy's other business records. However, this does not preclude a registrant from attaching a copy of the supplier's invoice to the related DEA Form 222.

Title 21 C.F.R. § 1305.15(a)(1) requires that, for orders using the DEA Form 222, an order must not be filled if the order is not complete, legible, or properly prepared, executed, or endorsed, or if the order shows any alteration, erasure, or change of any description. For a discussion of the circumstances in which an electronic order must not be filled see below, *Controlled Substance Ordering System (CSOS) - Electronic Order Forms*.

A supplier may refuse to accept an order for any reason as set forth under 21 C.F.R. § 1305.15(c). If a supplier refuses to accept an order, a statement that the order is not accepted is sufficient. If an order is refused, the supplier must return copies one and two of the DEA Form 222 to the purchaser with a statement explaining the reason the order was refused. For electronic orders, the supplier must notify the purchaser and provide a statement as to the reason (see below, *Controlled Substance Ordering System (CSOS) - Electronic Order Forms*).

DEA policy does not preclude the substitution of identical products differing in packaging size from those initially ordered, provided that the actual quantity received does not exceed the amount initially ordered and that the National Drug Code number reflected is that of the actual product shipped. For example, a distributor may substitute five bottles of 100, 2 milligram tablets for one bottle of 500, 2 milligram tablets or any variation thereof.

Cancellation and Voiding an Official Order Form

A purchaser may cancel an order (or partial order) on a DEA Form 222 by notifying the supplier in writing. The supplier must indicate the cancellation on Copies 1 and 2 of the DEA Form 222 by drawing a line through the cancelled item(s) and printing "cancelled" in the space provided for the number of items shipped.

A supplier may void part or all of an order on a DEA Form 222 by notifying the purchaser in writing. The supplier must indicate the voiding in Copies 1 and 2 of the DEA Form 222 by drawing a line through the cancelled item(s) and printing "void" in the space provided for the number of items shipped. For information regarding cancelled electronic orders, see below, *Controlled Substance Ordering System (CSOS) - Electronic Order Forms*.

Power of Attorney to Sign an Official Order Form

Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 by granting a power of attorney to each such individual. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute the DEA Forms 222.

The power of attorney may be revoked at any time by the person who granted and signed the power of attorney. Only if the renewal application is signed by a different person is it necessary to

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grant a new power of attorney when the pharmacy completes a renewal registration. The power of attorney should be filed with executed DEA Forms 222 as a readily retrievable record. The power of attorney is not submitted to DEA.

Suggested formats for granting and revoking a power of attorney follow:

Power of Attorney for DEA Forms 222 and Electronic Orders

(Name of registrant)

(Address of registrant)

(DEA registration number)

I, _____ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for schedule I and II controlled substances, in accordance with Section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact)

Witnesses:

1. _____
2. _____

Signed and dated on the _____ day of _____ in the year _____ at _____.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

(Signature of person revoking power)

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Witnesses:

1. _____
2. _____

Signed and dated on the _____ day of _____ in the year _____ at _____.

Lost or Stolen Order Forms

When a pharmacist has not received an expected shipment of controlled substances, he/she should first contact the supplier to determine whether the original DEA Form 222 was received. If the original order form has been lost or stolen, the pharmacist must complete a second order form so the supplier can fill the original order. The pharmacist must also prepare a statement which includes the first order form's serial number and date, and verify that the drugs ordered were never received. The pharmacy must attach a copy of the statement to the second order form that is sent to the supplier. In addition, the pharmacist must keep a copy of the statement with copy three from the first and second order forms.

A pharmacy, upon discovery of the loss or theft of used or unused order forms, must immediately report the loss to the local DEA Diversion Field Office (Appendix K) and provide the serial numbers of each lost or stolen order form. If an entire book or multiple books of order forms are lost or stolen, and the serial numbers of the missing forms cannot be identified, the pharmacist must report the approximate date of issuance (in lieu of the serial numbers) to the DEA. If an unused order form reported stolen or lost is later recovered or found, the pharmacy must immediately notify the local DEA Diversion Field Office.

Controlled Substance Ordering System (CSOS) - Electronic Order Forms

Any registrant permitted to order schedule II controlled substances may do so electronically via the DEA Controlled Substance Ordering System (CSOS) and maintain the records of these orders electronically for two years. The use of electronic orders is optional; registrants may continue to issue orders on a paper DEA Form 222. CSOS allows for secure electronic transmission of controlled substance orders without the supporting paper DEA Form 222. The adoption of the CSOS standards is the only allowance for the electronic transmission of schedule II controlled substance orders between controlled substance manufacturers, distributors, pharmacies, and other DEA authorized entities. CSOS uses Public Key Infrastructure (PKI) technology, which requires CSOS users to obtain a CSOS digital certificate for electronic ordering. The electronic orders must be signed using a digital signature issued by a Certification Authority (CA) run by the DEA.

Digital certificates can be obtained only by registrants and individuals granted power of attorney by registrants to sign orders. A registrant must appoint a CSOS coordinator who will serve as that registrant's recognized agent regarding issues pertaining to issuance of, revocation of, and changes to, digital certificates issued under that registrant's DEA registration. A CSOS digital certificate will be valid until the DEA registration under which it is issued expires or until the CSOS CA is notified that the certificate should be revoked. Certificates will be revoked if the certificate holder is no longer authorized to sign schedule II orders for the registrant, if the information on which the certificate is based changes, or if the digital certificate used to sign electronic orders has been compromised, stolen, or lost.

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A "Questions and Answers" page about the CSOS certificate is available on the DEA E-Commerce Program website at www.DEAecon.gov. Applicants can download the Diversion PKI CSOS Enrollment document and the CSOS Subscriber's Manual for assistance on the enrollment process. DEA maintains a support line to assist applicants and subscribers with issues pertaining to certificate enrollment, issuance, revocation, and renewal. Staff is available from 8:00 a.m. to 6:00 p.m. (Eastern Time), Monday through Friday at 1-877-332-3266 if further assistance is needed.

Unaccepted and Defective Electronic Orders

An electronic order for controlled substances may not be filled if any of the following occurs:

1. The required data fields have not been completed.
2. The order is not signed using a digital certificate issued by DEA.
3. The digital certificate used has expired or been revoked prior to signature.
4. The purchaser's public key will not validate the digital certificate.
5. The validation of the order shows that the order is invalid for any reason.

If an order cannot be filled, the supplier must notify the purchaser and provide a statement as to the reason (e.g., improperly prepared or altered). A supplier may, for any reason, refuse to accept any order. If a supplier refuses, a statement that the order is not accepted is sufficient.

When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original statement must be retained for two years. Neither a purchaser nor a supplier may correct a defective order. The purchaser must issue a new order for the order to be filled.

Cancellation and Voiding of Electronic Orders

A supplier may void all (or part) of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order and indicate "Void" on the copy and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled. The purchaser must retain an electronic copy of the voided order. Should a supplier partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided.

Lost Electronic Orders

If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement. This statement must include the unique tracking number and date of the lost order and state that the goods covered by the first order were not received through loss of that order. If the purchaser executes a new order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them both. If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is "not accepted" and return it to the purchaser. The purchaser must link the returned order to the record of that order and the statement.

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Ordering Schedules III-V Controlled Substances

The registrant must keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate. These receipts must also contain the name of each controlled substance, the finished form, the number of dosage units of finished form in each commercial container, and the number of commercial containers ordered and received. In addition, these receipts must be maintained in a readily retrievable manner for inspection by the DEA.

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SECTION IX - VALID PRESCRIPTION REQUIREMENTS

To dispense controlled substances, a pharmacist must know the requirements for a valid prescription which are described in this section. A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (i.e., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).

A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number.

The prescription must also include:

1. Drug name
2. Strength
3. Dosage form
4. Quantity prescribed
5. Directions for use
6. Number of refills authorized (if any)

A prescription must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual (i.e., secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature. The practitioner is responsible for ensuring the prescription conforms to all requirements of the law and regulations, both federal and state.

Who May Issue

A prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice, and
2. Registered with DEA or exempted from registration (e.g., Public Health Service, Federal Bureau of Prisons, military practitioners), or
3. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered, provided that additional requirements as set forth in the C.F.R. are met.

Purpose of Issue

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances.

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A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

Corresponding Responsibility

A pharmacist also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA (21 U.S.C. § 829). The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one's business or professional license (see *United States v. Kershman*, 555 F.2d 198 [United States Court Of Appeals, Eighth Circuit, 1977]).

Electronic Prescriptions

On March 31, 2010 the DEA published in the Federal Register an interim final rule *Electronic Prescriptions for Controlled Substances* which became effective June 1, 2010. The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are an addition to, not a replacement of, the existing rules.

Persons who wish to dispense controlled substances using electronic prescriptions must select software that meets the requirements of this rule. As of June 1, 2010, only those electronic pharmacy applications that comply with all of DEA's requirements as set forth in 21 C.F.R. §1311 may be used by DEA-registered pharmacies to electronically receive and archive controlled substances prescriptions and dispense controlled substances based on those prescriptions.

A registered pharmacy may process electronic prescriptions for controlled substances only if the following conditions are met:

1. The pharmacy uses a pharmacy application that meets all of the applicable requirements of 21 C.F.R. §1311, and
2. The prescription is otherwise in conformity with the requirements of the CSA and 21 C.F.R. §1311.

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A pharmacy cannot process electronic prescriptions for controlled substances until its pharmacy application provider obtains a third party audit or certification review that determines that the application complies with DEA's requirements and the application provider provides the audit/certification report to the pharmacy. The audit report the pharmacy will receive from the pharmacy application provider will indicate if the application is capable of importing, displaying, and storing DEA-required prescription information accurately and consistently. If the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display the information related to the name, address, and registration number of the practitioner, patient name and address, and prescription information (drug name, strength, quantity, directions for use), the indication of signing, and the number of refills, the pharmacy must not accept electronic prescriptions for the controlled substance.

If the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display **other information** required for prescriptions, the pharmacy must not accept electronic prescriptions for controlled substances that are subject to the additional information requirements. For example, until the audit or certification report indicates that the pharmacy application can import, display, and store both a hospital DEA number and the individual practitioner's extension number, the pharmacy must not accept electronic prescriptions that include only a hospital DEA registration number. The pharmacy may, however, use the application to process other controlled substance prescriptions if the audit or certification report has found that the pharmacy application meets all other requirements.

The pharmacy must determine which employees are authorized to enter information regarding the dispensing of controlled substance prescriptions and annotate or alter records of these prescriptions (to the extent such alterations are permitted under DEA regulations). The pharmacy must ensure that logical access controls in the pharmacy application are set so that only such employees are granted access to perform these functions.

When a pharmacist fills a prescription in a manner that would require, under 21 C.F.R. §1306, the pharmacist to make notation on the prescription if the prescription were a paper prescription, the pharmacist must make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record or linked files. ***When a prescription is received electronically, the prescription and all required annotations must be stored electronically.***

When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist must check the pharmacy's records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist must mark one as void.

When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to another pharmacy, the pharmacist must check with that pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy must mark the electronic version as void or cancelled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.

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Verification of Practitioner Registration

A pharmacist has a responsibility to ensure that a prescription has been issued by an appropriately registered or exempt practitioner (see above, *Who May Issue*). As such, it is helpful to be familiar with how a DEA registration number is constructed and to whom such registrations are issued.

Construction of Valid DEA Registration Number for Practitioners

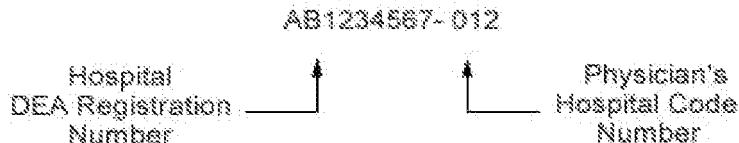
Knowing how a DEA registration number is constructed can be a useful tool for recognizing a forged prescription (see Appendix D, *Pharmacist's Guide to Prescription Fraud*). Prior to October 1, 1985, DEA registration numbers for physicians, dentists, veterinarians, and other practitioners started with the letter A. New registration numbers issued to practitioners after that date begin with the letter B or F. Registration numbers issued to mid-level practitioners begin with the letter M. The first letter of the registration number is almost always followed by the first letter of the registrant's last name (e.g., J for Jones or S for Smith) and then a computer generated sequence of seven numbers (such as MJ3614511).

Practitioner's Use of a Hospital's DEA Registration Number

Practitioners (e.g., intern, resident, staff physician, mid-level practitioner) who are agents or employees of a hospital or other institution, may, when acting in the usual course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in which he or she is employed, in lieu of individual registration, provided that:

1. The dispensing, administering, or prescribing is in the usual course of professional practice.
2. The practitioner is authorized to do so by the state in which they practice.
3. The hospital or institution has verified that the practitioner is permitted to administer, dispense, or prescribe controlled substances within the state.
4. The practitioner acts only within the scope of employment in the hospital or institution.
5. The hospital or institution authorizes the practitioner to administer, dispense, or prescribe under its registration and assigns a specific internal code number for each practitioner.

An example of a specific internal code number is depicted below:



A current list of internal codes and the corresponding individual practitioners is to be maintained by the hospital or other institution. This list is to be available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner. Pharmacists should contact the hospital or other institution for verification if they have any doubts in filling such a prescription.

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Exemption of Federal Government Practitioners from Registration

The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons, who is authorized to administer, dispense, or prescribe, but not to procure or purchase controlled substances in the course of his or her official duties. Such officials must follow procedures set forth in 21 C.F.R. part 1306 regarding prescriptions, but must also state the branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his or her Social Security identification number.

If federal government practitioners wish to maintain a DEA registration for a private practice, which would include prescribing for private patients, these practitioners must be fully licensed to handle controlled substances by the state in which they are located.

Registration Requirements for Mid-Level Practitioners

Mid-level practitioners (MLPs) are registered and authorized by the DEA and the state in which they practice to dispense, administer, and prescribe controlled substances in the course of professional practice (see Appendix B, *Definitions*). Examples of MLPs include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, physician assistants, optometrists, ambulance services, animal shelters, euthanasia technicians, nursing homes, and homeopathic physicians.

MLPs may apply for an individual DEA registration granting controlled substance privileges. However, such registration is contingent upon the authority granted by the state in which they are licensed. The DEA may register MLPs whose states clearly authorize them to prescribe, dispense, and administer controlled substances in one or more schedules.

It is incumbent upon the pharmacist who fills the prescription to ensure that the MLP is prescribing within the parameters established by the state in which he/she practices. MLP authority to prescribe controlled substances varies greatly by state. Pharmacists should check with the state licensing or controlled substances authority to determine which MLP disciplines are authorized to prescribe controlled substances in the state. Pharmacists may also visit the DEA Diversion website at www.DEAdiversion.usdoj.gov for a chart indicating the prescribing authority of MLPs by state (click on *Registration Support* and scroll down to *Mid-Level Practitioners Authorization by State*).

For electronic prescriptions written by mid-level practitioners, if required by State law, a supervisor's name and DEA number may be listed on the prescription, provided the prescription clearly indicates who is the supervisor and who is the prescribing practitioner.

Schedule II Controlled Substances

Schedule II controlled substances require a written prescription which must be manually signed by the practitioner or an electronic prescription that meets all DEA requirements for electronic prescriptions for controlled substances. There is no federal time limit within which a schedule II

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prescription must be filled after being signed by the practitioner. However, the pharmacist must determine that the prescription is still needed by the patient. While some states and many insurance carriers limit the quantity of controlled substances dispensed to a 30-day supply, there are no express federal limits with respect to the quantities of drugs dispensed via a prescription. However, the amount dispensed must be consistent with the requirement that a prescription for a controlled substance be issued only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. For a schedule II controlled substance, an oral order is only permitted in an emergency situation (see Section X, *Emergency Dispensing*).

Refills

The refilling of a prescription for a controlled substance listed in schedule II is prohibited (21 U.S.C. § 829(a)).

Issuance of Multiple Prescriptions for Schedule II Controlled Substances

The DEA has revised its regulations regarding the issuance of multiple prescriptions for schedule II controlled substances. Under the new regulation, which became effective December 19, 2007, an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance provided the following conditions are met:

1. Each prescription must be issued on a separate prescription blank.
2. Each separate prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.
3. The individual practitioner must provide written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription.
4. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.
5. The issuance of multiple prescriptions is permissible under applicable state laws.
6. The individual practitioner complies fully with all other applicable requirements under the CSA and C.F.R., as well as any additional requirements under state law.

It should be noted that the implementation of this change in the regulation should not be construed as encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Facsimile Prescriptions for Schedule II Controlled Substances

In order to expedite the filling of a prescription, a prescriber may transmit a schedule II prescription to the pharmacy by facsimile. The original schedule II prescription must be presented to the pharmacist and verified against the facsimile at the time the controlled substance is actually

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dispensed. The pharmacist must make sure the original document is properly annotated and filed with the records that are required to be kept.

Exceptions for Schedule II Facsimile Prescriptions

DEA has granted three exceptions to the facsimile prescription requirements for schedule II controlled substances. The facsimile of a schedule II prescription may serve as the original prescription as follows:

1. A practitioner prescribing a schedule II narcotic controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may transmit the prescription by facsimile. The pharmacy will consider the facsimile prescription a "written prescription" and no further documentation is required. All normal requirements of a legal prescription must be followed.
2. Practitioners prescribing schedule II controlled substances for residents of Long Term Care Facilities may transmit a prescription by facsimile to the dispensing pharmacy. The facsimile prescription serves as the original written prescription for the pharmacy. No further documentation is required.
3. A practitioner prescribing a schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state, may transmit a prescription to the dispensing pharmacy by facsimile. The practitioner will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription. No further documentation is required.

Schedules III-V Controlled Substances

A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets DEA's requirements for such prescriptions, or a call-in as indicated below (see *Telephone Authorization for Schedules III-V Controlled Substances*).

Refills

Schedules III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months after the date of issue. After five refills or after six months, whichever occurs first, a new prescription is required.

When a prescription for any controlled substance in schedules III or IV is refilled, the following information must be entered on the back of the prescription: the dispensing pharmacist's initials, the date the prescription was refilled, and the amount of drug dispensed on the refill. If the pharmacist only initials and dates the back of the prescription, the pharmacist will be deemed to have dispensed a refill for the full face amount of the prescription.

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Electronic Recordkeeping of Schedules III-IV Prescription Information

A pharmacy is permitted to use an electronic recordkeeping system for documenting refills as an alternative to the manual method for the storage and retrieval of original paper prescription orders for schedules III and IV controlled substances.

The electronic system must provide online retrieval of original prescription information for those prescriptions which are currently authorized for refill. The information must include, but is not limited to: the original prescription number; date of issuance; full name and address of the patient; the prescriber's name, address, and DEA registration number; the name, strength, dosage form and quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed); and the total number of refills authorized by the prescriber.

In addition, the electronic system must provide online retrieval of the current refill history for schedules III or IV controlled substance prescriptions. This information must include, but is not limited to: the name of the controlled substance, the date of refill, the quantity dispensed, the dispensing pharmacist's identification code or name/initials for each refill, and the total number of refills dispensed to date for that prescription.

The pharmacist must verify and document that the refill data entered into the system is correct. All computer generated prescription/refill documentation must be stored in a separate file at the pharmacy and must be maintained for a period of two years from the dispensing date. To meet the C.F.R. recordkeeping requirements, the pharmacy's electronic system must comply with the following guidelines:

1. If the system provides a hard copy printout of each day's controlled substance prescription refills, each pharmacist who refilled those prescriptions must verify his/her accuracy by signing and dating the printout as he/she would sign a check or legal document.
2. The printout must be provided to each pharmacy that uses the computer system within 72 hours of the date on which the refill was dispensed. The printout must be verified and signed by each pharmacist who dispensed the refills.
3. In lieu of such a printout, the pharmacy must maintain a bound logbook or a separate file in which each pharmacist involved in the day's dispensing signs a statement, verifying that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown.
4. A pharmacy's electronic system must have the capability of printing out any refill data which the pharmacy must maintain under the CSA. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance, by either brand or generic name or both, dispensed by the pharmacy. Such a printout must include:
 - Prescribing practitioner's name
 - Patient's name and address
 - Quantity and date dispensed on each refill
 - Name or identification code of the dispensing pharmacist
 - Original prescription number

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In any electronic system employed by a user pharmacy, the central recordkeeping location must be capable of providing a printout to a requesting pharmacy of the above information within 48 hours.

5. In case a pharmacy's electronic system experiences downtime, the pharmacy must have a back-up procedure to document in writing refills of schedules III or IV controlled substances. This procedure must ensure that refills are authorized by the original prescription, that the maximum number of refills has not been exceeded, and that all required data is retained for online entry as soon as possible.

A pharmacy may use only one of the two systems described (i.e., manual or electronic) for storage and retrieval of prescription order refill information of schedules III or IV controlled substances.

Facsimile Prescriptions for Schedules III-V Controlled Substances

Prescriptions for schedules III-V controlled substances may be transmitted by facsimile from the practitioner or the practitioner's agent to the dispensing pharmacy. The facsimile is considered to be equivalent to an original prescription as long as the practitioner has manually signed the prescription.

Telephone Authorization for Schedules III-V Prescriptions

A pharmacist may dispense a controlled substance listed in schedules III, IV, or V pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required for a valid prescription except for the signature of the practitioner (see Appendix D, *Pharmacist's Guide to Prescription Fraud*).

Transfer of Schedules III-V Prescription Information

A DEA registered pharmacy may transfer original prescription information for schedules III, IV, and V controlled substances to another DEA registered pharmacy for the purpose of refill dispensing between pharmacies, on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

Transfers are subject to the following requirements:

The transfer must be communicated directly between two licensed pharmacists and the transferring pharmacist must record the following information:

1. Write the word "VOID" on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.
2. Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record.

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3. Record the date of the transfer and the name of the pharmacist transferring the information.

For paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist, the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing all information required to be on a prescription and include:

1. Date of issuance of original prescription.
2. Original number of refills authorized on original prescription.
3. Date of original dispensing
4. Number of valid refills remaining and date(s) and locations of previous refill(s).
5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
6. Name of pharmacist who transferred the prescription.
7. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

For electronic prescriptions being transferred electronically, the transferring pharmacist must provide the receiving pharmacist with the following information in addition to the original electronic prescription data:

1. The date of the original dispensing
2. The number of refills remaining and the date(s) and locations of previous refills
3. The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.
4. The name of the pharmacist transferring the prescription.
5. The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.

The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription (listed above).

The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferal.

The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

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Prescription Monitoring Programs

A prescription monitoring program is a state-administered data collection system used to gather prescription information. This information may be made available to state and federal investigators on a need-to-know basis.

Many states have established an electronic prescription drug monitoring program because it has proven to be an effective tool for detecting pharmaceutical diversion and for developing pharmacist and physician medical education programs. These programs heighten awareness about diversion, prescription drug abuse, drug trends, and are useful for tracking prescription medication dispensed within a state. In some states, the data can be used by pharmacists to identify potential "doctor shoppers" and those who attempt to obtain controlled substances by fraud, forgery, or deceit.

In the states that have adopted these programs, a large part of their success has been attributed to the pharmacists' participation. The DEA strongly endorses prescription monitoring programs.

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SECTION X - DISPENSING REQUIREMENTS

Required Information for Prescription Labels

The pharmacist dispensing a prescription for a controlled substance listed in schedules II, III, IV, or V must affix to the package a label showing date of filling, the pharmacy name and address, the serial (prescription) number, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law. If a prescription is filled at a central fill pharmacy, the central fill pharmacy must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy.

Federal Food and Drug Administration regulations require that the label of any drug listed as a "controlled substance" in schedules II, III, or IV of the CSA must, when dispensed to or for a patient, contain the following warning: *CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.* In addition, a pharmacist who receives a prescription for a controlled substance must dispense that prescription to the patient or a member of the patient's household. To provide the controlled substance to anyone other than the patient or a member of the patient's household is distribution, not dispensing.

Schedule II Controlled Substance Prescriptions

A pharmacist may dispense a schedule II controlled substance, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except in an emergency situation as described below.

Emergency Dispensing

An "emergency prescription" in this context, is defined to mean that the immediate administration of the drug is necessary for proper treatment of the intended ultimate user, that no alternative treatment is available (including a drug which is not a schedule II controlled substance), and it is not possible for the prescribing practitioner to provide a written prescription for the drug at that time. In a bona fide emergency, a practitioner may telephone a schedule II prescription to the pharmacist who may then dispense the prescription. The prescribing practitioner must provide a written and signed prescription to the pharmacy within seven days and meet the below requirements:

1. The drug prescribed and dispensed must be limited to the amount needed to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription order.
2. The prescription order must be immediately reduced to writing by the pharmacist and must contain all information, except for the prescribing practitioner's signature.
3. If the prescribing individual practitioner is not known to the pharmacist, he/she must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner using his or her telephone number as listed in the telephone directory and/or other good faith efforts to insure his or her identity.

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4. Within seven days after authorizing an emergency telephone prescription, the prescribing practitioner must furnish the pharmacist a written, signed prescription for the controlled substance prescribed. The prescription must have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven day period. Upon receipt, the dispensing pharmacist must attach this written prescription to the oral emergency prescription which had earlier been reduced to writing by the pharmacist. By regulation, the pharmacist must notify the local DEA Diversion Field Office (Appendix K) if the prescriber fails to provide a written prescription within seven days. Failure of the pharmacist to do so will void the authority conferred on the pharmacy to dispense the controlled substance without a written prescription of a prescribing practitioner.
 5. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order.

Partial Dispensing

A prescription for a schedule II controlled substance may be partially dispensed if the pharmacist is unable to supply the full quantity of a written or emergency oral (telephone) prescription, provided the pharmacist notes the quantity supplied on the front of the written prescription, on a written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion may be dispensed within 72 hours of the first partial dispensing. However, if the remaining portion is not or cannot be filled within the 72 hour period, the pharmacist must notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

Partial Filling of Schedule II Prescriptions for Terminally Ill or Long Term Care Facility Patients

A prescription for a schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness, may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient.

The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" must be deemed to have been filled in violation of the CSA. For each partial filling, the dispensing pharmacist must record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in an LTCF or terminally ill patients are valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

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Schedules III-V Controlled Substance Prescriptions

A pharmacist may dispense a controlled substance in schedules III, IV, or V having received either a paper prescription signed by a practitioner, a facsimile of that prescription transmitted by the practitioner or their agent to the pharmacy, an electronic prescription that meets DEA's requirements for such prescriptions, or an oral prescription made by an individual practitioner. The pharmacist must promptly reduce the oral prescription to writing, including all required information except the signature of the prescribing practitioner.

Partial Dispensing

A pharmacist may partially dispense a prescription for schedules III-V controlled substances provided that each partial filling is recorded in the same manner as a refilling, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and no dispensing occurs beyond six months from the date on which the prescription was issued.

Dispensing Without a Prescription

Dispensing a controlled substance without a prescription is outlined in 21 C.F.R. § 1306.26. The regulation states that a controlled substance listed in schedules II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

1. Such dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his or her professional and legal responsibilities, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist);
2. Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance, nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance, may be dispensed at retail to the same purchaser in any given 48-hour period;
3. The purchaser is at least 18 years of age and the pharmacist requires every purchaser of a controlled substance under this section not known to him or her to furnish suitable identification (including proof of age where appropriate);
4. A bound record book (which must be maintained in accordance with the recordkeeping requirement of 21 C.F.R. § 1304.04) for dispensing of controlled substances is maintained by the pharmacist, which contains the name and address of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser;
5. The prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law; and
6. Central fill pharmacies may not dispense controlled substances at the retail level to a purchaser.

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Delivery of a Controlled Substance to Persons in Other Countries

Controlled substances that are dispensed pursuant to a legitimate prescription may not be delivered or shipped to individuals in other countries without proper authorization. Any such delivery or shipment is an export under the CSA and cannot be conducted unless the person sending the controlled substances:

1. Has registered with DEA as an "exporter" (see 21 C.F.R. §§ 1301 and 1309).
2. Has obtained the necessary permit(s), or submitted the necessary declaration(s) for export (21 C.F.R. §§ 1312 or 1313).

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SECTION XI - Ryan Haight Online Pharmacy Consumer Protection Act of 2008

Summary of the Act's Major Provisions

On October 15, 2008, the President signed into law the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008*, often referred to as the *Ryan Haight Act*. This law amends the CSA by adding a series of new regulatory requirements and criminal provisions designed to combat the proliferation of so-called “rogue Internet sites” that unlawfully dispense controlled substances by means of the Internet. The *Ryan Haight Act* applies to all controlled substances in all schedules.

This law became effective April 13, 2009. As of that date, it is illegal under federal law to deliver, distribute, or dispense a controlled substance by means of the Internet unless the online pharmacy holds a modification of DEA registration authorizing it to operate as an online pharmacy. Thus, any person who knowingly or intentionally dispenses a controlled substance by means of the Internet that does not have a modification of DEA registration allowing such activity is in violation of 21 U.S.C. § 841(h)(1) and subject to potential criminal prosecution and (in the case of DEA registrants) loss of DEA registration.

Note: The information contained in this section is meant to summarize the Ryan Haight Act but should not be relied upon as setting forth all the requirements. As is always the case, pharmacies are responsible for complying with the actual text of the CSA and DEA regulations.

Definition of an Online Pharmacy

An online pharmacy is a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet. Examples of an online pharmacy include (but are not limited to) the following:

- Any website that sells, or offers to sell, any controlled substance or a prescription therefor to a person in the United States.
- Any person who operates such a website.
- Any person who pays a practitioner to write prescriptions for controlled substances for customers of such a website.
- Any person who pays a pharmacy to fill prescriptions for controlled substances that were issued to customers of such a website.
- Any pharmacy that knowingly or intentionally fills prescriptions for controlled substances that were issued to customers of such a website.
- Any person who sends an e-mail that:
 - (1) offers to sell a controlled substance or a prescription for a controlled substance in a manner not authorized by the Act;

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- (2) directs buyers to a website operating in violation of the Act;
- (3) or otherwise causes or facilitates the delivery, distribution, or dispensing of a controlled substance in a manner not authorized by the Act.

Online Pharmacy Registration Exemptions

The following are exempt from the Ryan Haight Act's definition of an "online pharmacy" so long as their activities are limited solely to the exemptions provided:

- Manufacturers or distributors registered under 21 U.S.C. § 823(a), (b), (d), or (e) who do not dispense controlled substances to nonregistrants.
- Nonpharmacy practitioners who are registered under 21 U.S.C. § 823(f) and whose activities are authorized by that registration, provided that any website operated by such nonpharmacy practitioners complies with 21 C.F.R. § 1304.50, which requires the website to post in a visible and clear manner on its homepage, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, a list of the DEA-registered nonpharmacy practitioners who are affiliated with the website.
- Any hospital or other medical facility registered under 21 U.S.C. § 823(f) that is operated by an agency of the United States (including the Armed Forces).
- A health care facility owned or operated by an Indian tribe or tribal organization carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act.
- Any agent or employee of any hospital or facility that is operated by an agency of the United States, and any agent or employee of any hospital or facility owned or operated by an Indian tribe or tribal organization carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act, provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of such health care facilities only to the extent such individuals are furnishing services pursuant to those contracts or compacts.
- Mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance.
- A person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States.
- A pharmacy registered under 21 U.S.C. § 823(f) whose dispensing of controlled substances via the Internet consists solely of "refilling prescriptions for controlled substances in schedule III, IV, or V," **as that term is defined in 21 C.F.R. § 1300.04(k)**. (This definition is set forth at the end of this section.)

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- A pharmacy registered under 21 U.S.C. § 823(f) whose dispensing of controlled substances via the Internet consists solely of "filling new prescriptions for controlled substances in schedule III, IV, or V," **as that term is defined in 21 C.F.R. § 1300.04(d)**. (This definition is set forth at the end of this section.)
- Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of filling prescriptions that were electronically prescribed in a manner authorized by the CSA.
- Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of the transmission of prescription information between a pharmacy and an automated dispensing system located in a Long Term Care Facility when the registration of the automated dispensing system is held by that pharmacy as described in 21 C.F.R §§ 1301.17 and 1301.27 and the pharmacy is otherwise complying with the DEA regulations.

Notification Requirements

Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing by means of the Internet, the online pharmacy shall notify DEA and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances. Completion of the *Application for Modification of Registration for Online Pharmacies* serves as the notification requirement to DEA.

The online pharmacy must make a separate thirty-day advance notice to the State boards of pharmacy in each State in which it intends to offer to sell, deliver, distribute, or dispense controlled substances. Online pharmacies that apply for the modification of registration are required to certify that the applicable State boards of pharmacy have been notified.

How to Register as an Online Pharmacy

To operate legally as an online pharmacy, the online pharmacy must first be registered with DEA as a pharmacy. Once registered with DEA as a pharmacy, the pharmacy may apply for a modification of registration to operate as an online pharmacy. To apply for a modification of registration, complete the *Application for Modification of Registration for Online Pharmacies* online at www.DEAdviser.usdoj.gov. There is no fee to apply to modify a DEA registration to an online pharmacy.

If the modification of registration is approved, the pharmacy will be issued a modified DEA Certificate of Registration with the new business activity listed as online pharmacy. The registrant will keep the same DEA registration number. A pharmacy may perform the activities of a retail pharmacy and an online pharmacy at the same time.

State Licensure Requirements

An online pharmacy must comply with the requirements of all applicable State laws concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers,

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distributes, or dispenses, or offers to deliver, distribute, or dispense, controlled substances by means of the Internet. In addition, online pharmacies must certify they are in compliance with these requirements when completing the *Application for Modification of Registration for Online Pharmacies*.

The requirement that an online pharmacy list the States in which it is licensed to dispense controlled substances is designed to ensure that an online pharmacy only dispenses controlled substances to patients in States in which it is authorized to practice pharmacy. Dispensing beyond the scope of State licensure is one of the recurring transgressions of some rogue online pharmacies and generally violates State law. Under this Act, a State may bring civil action in federal court to enjoin any violation of the Ryan Haight Act - not merely those violations of State law - and to obtain other appropriate legal or equitable relief. 21 U.S.C. § 882(c).

Online Pharmacy Website Requirements

When a pharmacy applies for a modification of registration to become an online pharmacy, it must display on its homepage a declaration that it has done so. This declaration must state the following:

"In accordance with the Controlled Substances Act and the DEA regulations, this online pharmacy has made the notifications to the DEA Administrator required by 21 U.S.C. § 831 and 21 C.F.R. § 1304.40."

Once approved to operate as an online pharmacy, the online pharmacy must display at all times on the homepage of its Internet site a declaration of compliance with the requirements of 21 U.S.C. § 831 with respect to the delivery or sale or offer for sale of controlled substances. This statement must include the name of the pharmacy as it appears on the DEA Certificate of Registration.

An online pharmacy is required to post Internet Pharmacy Site Disclosure Information on the homepage of each Internet site it operates. It must be posted in a visible and clear manner and contain the following information:

1. The name and address of the pharmacy as it appears on the pharmacy's DEA Certificate of Registration.
2. The pharmacy's telephone number and e-mail address.
3. Name of pharmacist-in-charge, professional degree, States of licensure, and telephone number.
4. List of State(s) in which the pharmacy is licensed to dispense controlled substances.
5. Certification that the pharmacy is registered to deliver, distribute, or dispense controlled substances by means of the Internet.
6. The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.
7. The following statement must be visible on the website:

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"This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. § 829), or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. § 802(54))."

If at any time an online pharmacy should change its Internet site web address, the online pharmacy must notify DEA at least thirty days in advance of this change.

Reporting Requirements

Each online pharmacy must submit a monthly report to DEA of the total quantity of each controlled substance that the online pharmacy has dispensed the previous calendar month. The report is required for every month in which the total amount of dispensing of controlled substances by the pharmacy is either (i) over 100 prescriptions filled or (ii) 5,000 or more dosage units dispensed of all controlled substances combined. Should an online pharmacy's total quantity of dispensed controlled substances fall below both of the thresholds listed above, a report is still required that indicates a negative response for that given month.

The report must include the total amount of such dispensing by any means including all controlled substances dispensed via Internet transactions, mail-order transactions, face-to-face transactions, or any other means. It is not required that the online pharmacy identify the means of the dispensing in its report. Reporting will be by National Drug Code (NDC) numbers. Report the total number of dosage units dispensed for each NDC number.

This report is due on or before the 15th day of the following month. For example, an online pharmacy would submit its report for the month of January no later than February 15th. Reports must be submitted electronically via online reporting, electronic upload, or other means as approved by DEA. All reports must be kept for at least two years and be readily retrievable for inspection.

Should an online pharmacy revert back to a retail pharmacy, the pharmacy is still required to report the monthly sales for the month in which it changes back to a retail pharmacy.

Prescription Requirements

In order for a prescription to be valid, it must be issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient or by a covering practitioner. An in-person medical evaluation is a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

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Definition of Prescription Terms

A pharmacy website is exempted from the Ryan Haight Act's definition of an "online pharmacy" if its Internet-facilitated activity relating to controlled substances is limited to filling new and/or refilling prescriptions for controlled substances in schedules III, IV, or V. If the pharmacy is so exempted from the definition of an "online pharmacy," it is not required under the Act to obtain a modification of its DEA registration authorizing it to operate as an online pharmacy. Thus, it is important to understand precisely the definitions of the following terms.

Filling New Prescriptions for Controlled Substances in Schedules III-V

As stated in 21 C.F.R. § 1300.04 (d), the term "**filling new prescriptions for controlled substances in schedule III, IV, or V**" means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if:

1. The pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of [21 U.S.C. § 829(b) and (c)] and [21 C.F.R. §§ 1306.21 and 1306.22] (for purposes of this definition, such a prescription shall be referred to as the "original prescription");
2. The pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in [paragraph (1) of this definition] (i.e., the same controlled substance as described in [paragraph (1)]); and
3. The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

Refilling Prescriptions for Controlled Substances in Schedules III-V

As stated in 21 C.F.R. § 1300.04(k), the term "**refilling prescriptions for controlled substances in schedule III, IV, or V**:

1. Means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of [21 U.S.C. § 829(b) and (c)] and [21 C.F.R. §§ 1306.21 and 1306.22], as appropriate; and
2. Does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

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SECTION XII - OTHER PHARMACY OPERATIONS

Central Fill Pharmacy

A "central fill pharmacy" (see Appendix B, *Definitions*) fills prescriptions for controlled substances on behalf of retail pharmacies with which it has a contractual agreement to provide such services or with pharmacies who share a common owner. When one retail pharmacy receives a prescription and a second pharmacy prepares and subsequently delivers the controlled substance medication to the first retail pharmacy for dispensing to the patient, the second pharmacy is engaging in a "central fill" activity. Records must be maintained by both the central fill pharmacy and the retail pharmacy that completely reflect the disposition of all controlled substance prescriptions dispensed. Central fill pharmacies are required to comply with the same security requirements applicable to retail pharmacies including the general requirement to maintain effective controls and procedures to guard against theft and diversion of controlled substances. Retail pharmacies that also perform central fill activities are allowed to do so without a separate DEA registration, separate inventories, or separate records.

Central fill pharmacies are permitted to prepare both initial and refill prescriptions, subject to all applicable state and federal regulations. Only a licensed pharmacist may fill the prescription. Both the retail and central fill pharmacists have a corresponding responsibility to ensure that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and otherwise in the manner specified by DEA regulations.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. Prescriptions for controlled substances listed in schedules II, III, IV, or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

1. Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;
2. Ensure that all information required to be on a prescription is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
3. Maintain the original prescription for a period of two years from the date the prescription was last refilled;
4. Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the retail pharmacy employee accepting delivery;
5. For schedules III-V prescriptions, indicate in the information transmitted the number of refills already dispensed and the number of refills remaining (refills for schedule II prescriptions are not permitted).

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The central fill pharmacy receiving the transmitted prescription must:

1. Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and the DEA registration number of the retail pharmacy transmitting the prescription;
2. Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription; and
3. Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e. private, common, or contract carrier).

Central fill pharmacies must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy. Central fill pharmacies must comply with the provisions of the C.F.R. when selecting private, common, or contract carriers to transport filled prescriptions to a retail pharmacy (and likewise for retail pharmacies retrieving filled prescriptions from a central fill pharmacy) for delivery to the ultimate user.

For electronic prescriptions, the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal must be added to the electronic prescription record.

Long Term Care Facilities

A Long Term Care Facility (LTCF) is defined in the C.F.R. as a nursing home, retirement care, mental care, or other facility or institution, which provides extended health care to resident patients. In most cases, these facilities are not registered with DEA, yet these health care facilities routinely maintain controlled substances issued via prescription to their residents. These controlled substances are already outside the CSA's closed drug distribution system since they have been dispensed to the ultimate user.

LTCFs frequently need to dispose of unused medications due to a change in the resident's medication or the resident's death. Accordingly, LTCFs should contact the local DEA Diversion Field Office (Appendix K) for drug disposal instructions. The DEA is aware of issues currently facing LTCFs concerning the dispensing and handling of controlled substances, which are affected by a variety of state laws and circumstances. Pharmacists should check with their state agency for guidelines concerning controlled substances at LTCFs.

Regulations concerning LTCFs can also be found under:

- Section IX, *Exceptions for Schedule II Facsimile Prescriptions*
- Section X, *Partial Filling of Schedule II Prescriptions for Terminally Ill or Long Term Care Facility Patients*

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Use of Automated Dispensing Systems by Retail Pharmacies at Long Term Care Facilities

If state law or regulations permit, the DEA will allow a retail pharmacy to register at the site of the LTCF and store controlled substances in an Automated Dispensing System (ADS) as outlined in 21 C.F.R. § 1301.27. In an ADS, a pharmacy stores bulk drugs in the machine in separate bins or containers. The pharmacy programs and controls the ADS remotely. Only authorized LTCF staff are allowed access to its contents, which are dispensed on a single-dose basis at the time of administration pursuant to a valid prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs are not considered dispensed until the system provides them, drugs in the ADS are counted as pharmacy stock. A registered retail pharmacy that possesses additional registrations for ADS machines at LTCFs may keep all records required for those additional registered sites at the retail pharmacy or other approved central location.

DEA registered pharmacies wishing to operate an ADS at an LTCF must contact the DEA Office of Diversion Control, Registration Section, at 1-800-882-9539 for registration instructions. Additional requirements for maintaining an ADS can be found online at www.DEAdiversion.usdoj.gov.

Emergency Kits for Long Term Care Facilities

The DEA has issued a policy statement which provides individual state licensing and regulatory boards with general guidelines for establishing specific rules concerning controlled substances used in emergency kits at Long Term Care Facilities (see Appendix H, *Guidelines for Emergency Kits in Long Term Care Facilities*).

Opioid (Narcotic) Addiction Treatment Programs

The Narcotic Addiction Treatment Act of 1974 and the Drug Addiction Treatment Act (DATA) of 2000 amended the CSA with respect to the use of controlled substances in the medical treatment of opioid addiction. These laws established the procedures for approving and licensing practitioners involved in the treatment of opioid addiction as well as improving the quality and delivery of that treatment to the segment of society in need.

Practitioners wishing to prescribe and dispense FDA approved schedule II controlled substances (i.e., methadone) for maintenance and detoxification treatment must obtain a separate DEA registration as a Narcotic Treatment Program via a DEA Form 363 which may be completed online at www.DEAdiversion.usdoj.gov. In addition to obtaining this separate DEA registration, this type of activity also requires the approval and certification by the Center for Substance Abuse Treatment (CSAT) within the Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services as well as the applicable state methadone authority.

If a practitioner wishes to prescribe or dispense schedules III, IV, or V controlled substances approved by the FDA for addiction treatment (i.e., Suboxone® or Subutex® drug products), the practitioner must request a waiver from CSAT which will then notify DEA of all waiver requests. These practitioners are referred to as DATA waived practitioners.

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DATA waived practitioners may treat 30 or 100 patients at any one time, dependent on individual authorization from CSAT. Upon authorization by CSAT, DEA will issue a new DEA certificate of registration bearing (1) the DEA registration number, (2) a unique identification number, and (3) the corresponding business activity to identify whether the physician is authorized to treat 30 or 100 patients. Pursuant to 21 C.F.R. §1301.28(d), the practitioner is required to include the identification number on all records when dispensing and on all prescriptions when prescribing Schedules III, IV, or V narcotic controlled drugs for use in maintenance or detoxification treatment. The listing of the identification number on a prescription is in addition to all other information required on a valid prescription to include the practitioner's DEA registration number (see Section IX, *Valid Prescription Requirements*).

Dispensing Controlled Substances for the Treatment of Pain

On September 6, 2006, the DEA published in the Federal Register a Policy Statement, *Dispensing Controlled Substances for the Treatment of Pain*. The purpose of the Policy Statement was to make clear the longstanding requirement under the law that physicians may prescribe controlled substances only for a legitimate medical purpose in the usual course of professional practice. In no way should this interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate pain treatment. The second purpose of the Policy Statement was for the DEA to dispel the mistaken notion among a small number of medical professionals that the agency has embarked on a campaign to "target" physicians who prescribe controlled substances for the treatment of pain or that physicians must curb their legitimate prescribing of pain medications to avoid legal liability.

To achieve these aims, the document summarized the relevant legal principles and provided an explanation of DEA's role with respect to the regulation of controlled substances. The document also addressed specific issues and questions that have been raised on a recurring basis by physicians who seek guidance on the subject of dispensing controlled substances for the treatment of pain.

To review the Policy Statement, it may be accessed at www.DEAdiversion.usdoj.gov. Click on *Info & Legal Resources*, then *Federal Register Notices*, then *Notices 2006*, then *Policy Statement: Dispensing Controlled Substances for the Treatment of Pain, September 6, 2006*. For additional guidance on the responsibilities of the pharmacist where it pertains to the treatment of pain, see Section IX, *Corresponding Responsibility*.

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SECTION XIII - OTHER CONTROLLED SUBSTANCE REGULATIONS

Controlled Substance Distribution by a Pharmacy - "Five Percent Rule"

A pharmacy registered to dispense controlled substances may distribute such substances (without being registered as a distributor) to another pharmacy or to a registered practitioner for the purpose of general dispensing by the practitioner to patients, provided that the following conditions are met:

1. The pharmacy or practitioner that will receive the controlled substances is registered under the CSA to dispense controlled substances;
2. The distribution is recorded by the distributing practitioner in accordance with 21 C.F.R. § 1304.22(c) and the receipt is recorded by the receiving practitioner in accordance with 21 C.F.R. § 1304.22(c);
3. If the pharmacy distributes a schedule II controlled substance, it must document the transfer on an official order form (DEA Form 222) or the electronic equivalent. For instructions on completing this form, see Section VIII, *Ordering Controlled Substances*.
4. **"Five Percent Rule"** - total number of dosage units of all controlled substances distributed by a pharmacy may not exceed five percent of all controlled substances dispensed by the pharmacy during a calendar year. If at any time the controlled substances distributed exceed five percent, the pharmacy is required to register as a distributor.

United States Postal Service Mailing Requirements for Controlled Substances

United States Postal Services regulations permit the mailing of controlled substances by drug manufacturers or their agents, pharmacies, or other authorized handlers when distribution is lawful under DEA regulations and if the mailer or the addressee meets one of the following conditions:

1. The mailer or the addressee is registered with DEA.
2. The mailer or the addressee is exempt from DEA registration as permissible by law.

United States Postal Service regulations permit mailing of any controlled substance, provided it is not outwardly dangerous and will not cause injury to a person's life or health, and if the following preparation and packaging standards are met:

1. The inner container of any parcel containing controlled substances is marked and sealed as required by the provisions of the CSA and its implementing regulations, and is placed in a plain outer container or securely wrapped in plain paper.
2. If the controlled substance consists of prescription medicines, the inner container is also labeled to show the name and address of the pharmacy, practitioner, or other person dispensing the prescription.
3. The outside wrapper or container is free of markings that would indicate the nature of the contents.

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SECTION XIV - COMBAT METHAMPHETAMINE EPIDEMIC ACT OF 2005

Summary of the Act's Major Provisions

In March 2006, the President signed the *Combat Methamphetamine Epidemic Act of 2005* (CMEA). As a result of the new law, the DEA issued an Interim Final Rule in the Federal Register on September 26, 2006, which outlined the retail provisions of the CMEA.

Under the CMEA, regulated sellers must follow new requirements for retail sales of over-the-counter products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine (PPA), which can be used to manufacture methamphetamine illegally. The CMEA defined "*regulated seller*" to mean a retail distributor (including a pharmacy and mobile retail vendors) and "*at retail*" to mean sale or purchase for personal use.

Scheduled Listed Chemical Products

The CMEA created a new category of products called "*scheduled listed chemical product (SLCP)*." It includes any product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug that contains ephedrine, pseudoephedrine, or PPA (includes salts, optical isomers, and salts of optical isomers) (21 U.S.C. § 802(45)). This applies to nonprescription drug products only, not prescription drug products. Retail sales of SLCPs are excluded from the definition of a "regulated transaction" and from the registration requirement under 21 U.S.C. § 823, but are subject to a separate system of retail sales controls under 21 U.S.C. § 830.

Other requirements of the law include:

- Requirement of regulated sellers to place the products behind the counter or in locked cabinets.
- Requirement of regulated sellers to check the identity of purchasers and maintain a log of each sale that includes the purchaser's name and address, signature of the purchaser, product sold, quantity sold, date, and time.
- Requirement of regulated sellers to maintain the logbook for at least two years.
- Requirement of regulated sellers to train employees in the requirements of the law and certify to DEA that the training has occurred.
- Places a quantity limit of each of the chemicals that may be sold to an individual in a day to 3.6 grams of the chemical (base) without regard to the number of transactions.
- For nonliquids, product packaging is limited to blister packs containing no more than 2 dosage units per blister. Where blister packs are not technically feasible, the product must be packaged in unit dose packets or pouches.
- For individuals, purchases in a 30-day period are limited to 9 grams, of which not more than 7.5 grams may be imported by means of a common or contract carrier or the U.S. Postal Service.

While many states have enacted their own legislation regarding the regulation of these products, the federal law also requires regulated sellers to complete a self-certification process with the DEA that includes training their employees on the new regulations and procedures. The self-certification

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process must be completed online at www.DEAdiversion.usdoj.gov. If state law differs from federal law regarding the regulation of these products, retail outlets are to adhere to the stricter provisions of both.

Copies of the Interim Final Rule are available at www.DEAdiversion.usdoj.gov (click on the *Combat Meth Act of 2005*, then *Interim Final Rule - Retail Sales of Scheduled Listed Chemical Products*). Details on specific provisions of the CMEA that may impact a pharmacy that engages in retail sales of SLCPs are outlined below.

Recordkeeping Requirements

Regulated sellers are required to maintain a written (bound logbook) or electronic list of sales that identifies the transactions with the following information:

1. The name of the purchaser
2. The address of the purchaser
3. The date and time of the sale
4. The amount of product sold

The logbook requirement does not apply to any purchase by an individual of a single sales package that contains not more than 60 milligrams of pseudoephedrine.

Concurrently, purchasers are required to:

1. Present a photo identification issued by a State or the Federal Government (see *Proof of Identity Requirements* below for a complete list of acceptable forms of identification).
2. Sign a logbook and enter his or her name, address, date, and time of sale.

Once identification of the purchaser is presented to the seller, the seller is required to:

1. Determine that the name in the logbook corresponds to the name on the identification and that the date and time are correct.
2. Enter into the logbook the name of the product and the quantity sold.

The logbook must include a notice to purchasers that entering false statements or misrepresentations in the logbook may subject purchasers to criminal penalties under 18 U.S.C. § 1001. Sellers must maintain each entry in the logbook for not fewer than two years after the date on which the entry is made.

Loss or Theft of Scheduled Listed Chemical Products

A report should be made orally to the local DEA Diversion Field Office (Appendix K) in the area where the pharmacy is located. Per 21 C.F.R. § 1314.15(c), a written report of losses must be filed within 15 days after the pharmacist becomes aware of the loss or theft. A written report should include the DEA registration number (if applicable), name, business address, date of loss, type of loss, and a description of the circumstances of the loss (e.g., in-transit, theft from premises).

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Proof of Identity Requirements

The CMEA requires an individual to present an identification card that includes a photograph and is issued by a State or the Federal Government or a document considered acceptable under 8 C.F.R. § 274a.2(b)(1)(v)(A) and (B). Those documents currently include the following:

- United States passport;
- Alien Registration Receipt Card or Permanent Resident Card, Form I-551;
- An unexpired foreign passport that contains a temporary I-551 stamp, or temporary I-551 printed notation on a machine-readable immigrant visa;
- An Employment Authorization Document which contains a photograph (Form I-766);
- In the case of a nonimmigrant alien authorized to work for a specific employer incident to status, a foreign passport with form I-94 or Form I-94A bearing the same name as the passport and containing an endorsement of the alien's nonimmigrant status, as long as the period of endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified on the Form;
- A passport from the Federated States of Micronesia (FSM) or the Republic of the Marshall Islands (RMI) with Form I-94 or Form I-94A indicating nonimmigrant admission under the Compact of Free Association Between the United States and the FSM or RMI;
- In the case of an individual lawfully enlisted for military service in the Armed Forces under 10 U.S.C. § 504, a military identification card issued to such individual may be accepted only by the Armed Forces.

For individuals 16 years of age or older:

- A driver's license or identification card containing a photograph, issued by a state or an outlying possession of the United States. If the driver's license or identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address;
- School identification card with a photograph;
- Voter's registration card;
- U.S. military card or draft record;
- Identification card issued by federal, state, or local government agencies or entities. If the identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address;
- Military dependent's identification card;
- Native American tribal documents;
- United States Coast Guard Merchant Mariner Card;
- Driver's license issued by a Canadian government authority.

For individuals under age 18 who are unable to produce a document from the list above, the following documents are acceptable to establish identity only:

- School record or report card;
- Clinic doctor or hospital record;
- Daycare or nursery school record.

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NOTE: The list of acceptable forms of identification, as cited in the CMEA, may change ("in effect on or after the date of enactment"). The DEA has no discretion to alter the list.

Product Placement

SLCPs must be stored behind the counter or, if in an area where the public has access, in a locked cabinet. Although DEA is not including cabinet specifications in the rule, a locked cabinet should be substantial enough that it cannot be easily picked up and removed. In a store setting, the cabinet should be similar to those used to store items, such as cigarettes, that can be accessed only by sales staff.

Self-Certification

As part of the requirements of CMEA, an annual self-certification is required for all regulated sellers of SLCPs. A regulated seller must not sell SLCPs unless it has self-certified with DEA. In self-certifying, the regulated seller is confirming:

- The employees who will be engaged in the sale of SLCPs have undergone training regarding provisions of CMEA.
- Records of the training are maintained.
- Sales to individuals do not exceed 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine per day.
- Nonliquid forms are packaged as required.
- SLCPs are stored behind the counter or in a locked cabinet.
- A written or electronic logbook containing the required information on sales of these products is properly maintained.
- The logbook information will be disclosed only to Federal, State, or local law enforcement and only to ensure compliance with Title 21 of the United States Code or to facilitate a product recall.

The only way to self-certify is through DEA's Diversion website at www.DEAdiversion.usdoj.gov. Self-certification can be accomplished on any computer (e.g., at the store, at home, at the library, or at any other location).

A certificate will be generated by DEA upon receipt of the self-certification application. The regulated seller may print this certificate, or if the regulated seller is unable to print it, DEA will print and mail the certificate to the regulated seller. Chain stores wishing to file self-certifications for more than 10 locations must print or copy the form electronically and submit the information to DEA by mail. DEA will work with these persons to facilitate this process. Persons interested in this self-certification option should contact DEA for assistance at 1-800-882-9539. For current DEA registrants, the system will pre-populate the form with basic information if the registrant enters his DEA registration number in the field provided.

The regulated seller must self-certify to DEA as described above on an **annual basis**. It is the responsibility of the regulated seller to ensure that all employees have been trained prior to self-certifying each time.

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It is the regulated seller's responsibility to annually renew before the certificate expires if the regulated seller intends to continue selling SLCPs at retail. The certificate contains a self-certification number in the upper right corner. The expiration date of the certificate is listed under the self-certification number. Regulated sellers may verify the expiration date of their certificate at www.DEAdiversion.usdoj.gov.

The self-certification requirement is subject to the provisions of 18 U.S.C. § 1001. A regulated seller who knowingly or willfully certifies to facts that are not true is subject to fines and imprisonment.

Required Training

Training materials designed by DEA must be used, although a regulated seller may include information in addition to that provided by DEA. DEA training materials may be found at www.DEAdiversion.usdoj.gov.

Training Records

Each employee of a regulated seller who is responsible for delivering SLCPs to purchasers or who deals directly with purchasers by obtaining payment for the SLCPs must undergo training and must sign an acknowledgement of training received prior to selling SLCPs. This record must be kept in the employee's personnel file.

Self-Certification Fee

On December 29, 2008, the DEA published a Final Rule in the Federal Register entitled *Combat Methamphetamine Epidemic Act of 2005: Fee for Self-Certification for Regulated Sellers of Scheduled Listed Chemical Products*. The rule established a self-certification fee for regulated sellers of SLCPs that are not DEA pharmacy registrants.

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APPENDICES

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APPENDIX A

This summary is provided as a quick reference to the provisions of the Controlled Substances Act. It is not intended to replace any statutory or regulatory requirement thereof. For complete guidance as to the provisions of each area indicated below, please check the appropriate section of this manual.

Summary of Controlled Substances Act Requirements

| | Schedule II | Schedules III & IV | Schedule V |
|---|--|--|---|
| <i>Registration</i> | Required | Required | Required |
| <i>Receiving Records</i> | DEA Form 222 | Invoices, readily retrievable | Invoices, readily retrievable |
| <i>Prescriptions</i> | Written ¹ prescriptions ² | Written, oral, or fax | Written, oral, or fax |
| <i>Refills</i> | No | No more than 5 within 6 months | As authorized when prescription is issued or if renewed by a practitioner |
| <i>Maintenance of Prescriptions</i> | Separate file | Separate file or readily retrievable | Separate file or readily retrievable ³ |
| <i>Distribution Between Registrants</i> | DEA Form 222 | Invoices | Invoices |
| <i>Security</i> | Locked cabinet or dispersed among non-controlled pharmaceuticals | Locked cabinet or dispersed among non-controlled pharmaceuticals | Locked cabinet or dispersed among non-controlled pharmaceuticals |
| <i>Theft or Significant Loss</i> | Report to DEA and complete DEA Form 106 | Report to DEA and complete DEA Form 106 | Report to DEA and complete DEA Form 106 |

Note: **All records** must be maintained for 2 years, unless state law requires a longer period.

¹ Written prescriptions include paper prescriptions and electronic prescriptions that meet DEA's requirements for such prescriptions.

² Emergency prescriptions require a signed follow-up prescription within seven days.

Exceptions: A facsimile prescription serves as the original prescription when issued to residents of Long Term Care Facilities, hospice patients, or patients with a diagnosed terminal illness, or for immediate administration (21 C.F.R. § 1306.11(e), (f) and (g)).

³ The record of dispensing can also be a schedule V logbook, if state law allows.

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APPENDIX B

Definitions Based on the Controlled Substances Act and the Code of Federal Regulations

Administer

The direct application of a controlled substance to the body of a patient or research subject by 1) a practitioner or (in his/her presence) by his/her authorized agent, or 2) the patient or research subject at the direction and in the presence of the practitioner, whether such application is by injection, inhalation, ingestion, or any other means.

Central Fill Pharmacy

A pharmacy which is permitted by the state in which it is located to prepare controlled substance orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

Chemicals

Please see the definitions for List I Chemical, Retail Distributor and Scheduled Listed Chemical Product.

Dispense

To deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

Individual Practitioner

A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

Institutional Practitioner

A hospital or other person (other than an individual) licensed, registered or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

Inventory

All factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

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List I Chemical

A chemical specifically designated by the [DEA] Administrator in 21 C.F.R. § 1310.02(a)... that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the [Controlled Substances] Act and is important to the manufacture of a controlled substance.

Long Term Care Facility (LTCF)

A nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

Mid-level Practitioner (MLP)

An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of MLPs include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants who are authorized to dispense controlled substances by the state in which they practice. Because this authority varies greatly by state, check with the state licensing authority to determine which MLP disciplines are authorized to dispense controlled substances in a particular state or visit, www.DEAdviser.usdoj.gov (click on *Registration Support*, then *Resources*, then *Mid-level Practitioners Authorization by State*).

Online Pharmacy

An online pharmacy is a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet.

Pharmacist

Any pharmacist licensed by a state to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by such state.

Prescription

An order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

Readily Retrievable

Certain records which are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

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Regulated Seller

A retail distributor (including a pharmacy or a mobile retail vendor), except that the term does not include an employee or agent of the distributor.

Retail Distributor

A grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing ephedrine, pseudoephedrine or phenylpropanolamine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

Scheduled Listed Chemical Product (SLCP)

A product that contains ephedrine, pseudoephedrine, or phenylpropanolamine which may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug. Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers.

Ultimate User

A person who has lawfully obtained, and who possesses, a controlled substance for his [her] own use or for the use of a member of his [her] household or for an animal owned by him [her] or by a member of his [her] household.

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APPENDIX C

Definitions of Abbreviations

C.F.R.....Code of Federal Regulations
CMEA.....Combat Methamphetamine Epidemic Act of 2005
CSA.....Controlled Substances Act
CSATCenter for Substance Abuse Treatment
CSOS.....Controlled Substance Ordering System
CSRPA.....Controlled Substance Registrant Protection Act of 1984
DEA.....Drug Enforcement Administration
FDA.....Food and Drug Administration
HHSDepartment of Health and Human Services
SAMHSA.....Substance Abuse and Mental Health Services Administration
U.S.C.United States Code

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APPENDIX D

Pharmacist's Guide to Prescription Fraud

The purpose of this guide is to ensure that controlled substances continue to be available for legitimate medical and scientific purposes while preventing diversion into the illicit market. It is not the intent of this publication to discourage or prohibit the use of controlled substances where medically indicated. However, nothing in this guide should be construed as authorizing or permitting any person to conduct any act that is not authorized or permitted under federal or state laws.

Pharmacist's Responsibilities

The abuse of prescription drugs—especially controlled substances—is a serious social and health problem in the United States today. As a healthcare professional, pharmacists share responsibility for preventing prescription drug abuse and diversion.

- Pharmacists have a personal responsibility to protect their practice from becoming an easy target for drug diversion. They need to know of the potential situations where drug diversion can occur, and establish safeguards to prevent drug diversion.
- The dispensing pharmacist must maintain a constant vigilance against forged or altered prescriptions. The CSA holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment.

Types of Fraudulent Prescriptions

Pharmacists should be aware of the various kinds of forged prescriptions that may be presented for dispensing. Some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the practitioner's prescription. They may have prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice to verify the prescription. Drug seeking individuals may also call in their own prescriptions and give their own telephone number as a call-back for confirmation. Drug abusers sometimes steal legitimate prescription pads from practitioner's offices and/or hospitals and prescriptions are written using fictitious patient names and addresses.

In addition, individuals may go to emergency rooms complaining of pain in the hopes of receiving a controlled substance prescription. The prescription can then be altered or copied to be used again. Computers are often used to create prescriptions for nonexistent doctors or to copy legitimate doctors' prescriptions. The quantity of drugs prescribed and frequency of prescriptions filled are not lone indications of fraud or improper prescribing, especially if a patient is being treated with opioids for pain management. Pharmacists should also recognize that drug tolerance and physical dependence may develop as a consequence of a patient's sustained use of opioid analgesics for the legitimate treatment of chronic pain.

The following criteria may indicate that a prescription was not issued for a legitimate medical purpose:

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- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the area.
- The patient appears to be returning too frequently. A prescription which should last for a month in legitimate use is being refilled on a biweekly, weekly or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "uppers and downers" at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- People who are not regular patrons or residents of the community, show up with prescriptions from the same physician.

The following criteria may indicate a forged prescription:

- Prescription looks "too good". The prescriber's handwriting is too legible.
- Quantities, directions, or dosages differ from usual medical usage.
- Prescription does not comply with the acceptable standard abbreviations or appears to be textbook presentations.
- Prescription appears to be photocopied.
- Directions are written in full with no abbreviations.
- Prescription is written in different color inks or written in different handwriting.

Prevention Techniques

- Know the prescriber and his/her signature.
- Know the prescriber's DEA registration number.
- Know the patient.
- Check the date on the prescription order to determine if it has been presented in a reasonable length of time since being issued by the prescriber.

When there is a question about any aspect of the prescription order, the pharmacist should contact the prescriber for verification or clarification.

If at any time a pharmacist is in doubt, he /she should require proper identification. Although this procedure is not foolproof (identification papers can also be stolen/forged), it does increase the drug abuser's risk. If a pharmacist believes the prescription is forged or altered, he/she should not dispense it and call the local police. If a pharmacist believes he/she has discovered a pattern of prescription abuse, he/she should contact the state Board of Pharmacy or the local DEA Diversion Field Office (Appendix K). Both DEA and state authorities consider retail-level diversion a priority issue.

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Proper Controls

Dispensing procedures without control and professional caution are an invitation to the drug abuser. Proper controls can be accomplished by following common sense, sound professional practice, and proper dispensing procedures. In addition, pharmacy staff should have knowledge of these safeguards, as it will help prevent and protect the pharmacy from becoming a source of diversion.

Most drug abusers seek out areas where communication and cooperation between health care professionals are minimal because it makes the drug abuser's work easier. Thus, a pharmacist should encourage other local pharmacists and physicians to develop a working relationship which will promote teamwork and camaraderie. In addition, the pharmacist should become familiar with those controlled substances that are popular for abuse and resale on the streets in the area and should discuss those findings with other pharmacists and practitioners in the community.

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APPENDIX E

Affidavit for a New Pharmacy¹

I, _____, the _____ (Title of officer, official, partner, or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) at _____ (Number and Street), _____ (City) _____ (State) _____ (Zip Code), hereby certify that said store was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy or Licensing Agency) of the State of _____ on _____ (Date).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number. I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. § 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under 21 U.S.C. § 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than \$30,000.00 or both.

Signature (Person who signs Application for Registration)

State of _____ County of _____ Subscribed to and sworn before me this _____ day of _____, 20_____.

Notary Public

¹ 21 C.F.R. § 1301.17(a)

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APPENDIX F

Affidavit for Transfer of a Pharmacy¹

I, _____, the _____ (Title of officer, official, partner, or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) hereby certify:

(1) That said company was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy or Licensing Agency) of the State of _____ and a DEA Registration Number _____ for a pharmacy located at _____ (Number and Street),
_____ (City) _____ (State) _____ (Zip Code); and

(2) That said company is acquiring the pharmacy business of _____ (Name of Seller) doing business as _____ with DEA Registration Number _____ on or about _____ (Date of Transfer) and that said company has applied (or will apply on _____ (Date)) for a pharmacy permit from the Board of Pharmacy (or Licensing Agency) of the State of _____ to do business as _____ (Store name) at _____ (Number and Street) _____ (City)
_____ (State) _____ (Zip Code).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number.

I understand that if a DEA registration number is issued, the pharmacy may acquire controlled substances but may not dispense them until a pharmacy permit or license is issued by the State board of pharmacy or licensing agency.

I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. § 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under 21 U.S.C. § 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than \$30,000.00 or both.

Signature (Person who signs Application for Registration)

State of _____ County of _____ Subscribed to and sworn before me
this _____ day of _____, 20 _____.

Notary Public

¹ 21 C.F.R. § 1301.17(b)

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APPENDIX G

**Equivalency Tables for Ephedrine, Pseudoephedrine, and Phenylpropanolamine Under the
Combat Methamphetamine Epidemic Act of 2005**

| RETAIL DAILY SALE LIMITS ARE NOT TO EXCEED THE FOLLOWING AMOUNTS PER PURCHASER | |
|---|--|
| Ingredient | Number of Tablets = 3.6 grams |
| 25 mg Ephedrine HCl | 175 |
| 25 mg Ephedrine Sulfate | 186 |
| 30 mg Pseudoephedrine HCl | 146 |
| 60 mg Pseudoephedrine HCl | 73 |
| 120 mg Pseudoephedrine HCl | 36 |
| 30 mg Pseudoephedrine Sulfate | 155 |
| 60 mg Pseudoephedrine Sulfate | 77 |
| 120 mg Pseudoephedrine Sulfate | 38 |
| Phenylpropanolamine (PPA) | The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only. |

| 30-DAY SALE LIMITS ARE NOT TO EXCEED THE FOLLOWING AMOUNTS PER PURCHASER | | |
|---|--|--|
| Ingredient | Number of tablets at retail = 9 grams | Number of tablets for mail orders = 7.5 grams |
| 25 mg Ephedrine HCl | 439 | 366 |
| 25 mg Ephedrine Sulfate | 466 | 389 |
| 30 mg Pseudoephedrine HCl | 366 | 305 |
| 60 mg Pseudoephedrine HCl | 183 | 152 |
| 120 mg Pseudoephedrine HCl | 91 | 76 |
| 30 mg Pseudoephedrine Sulfate | 389 | 324 |
| 60 mg Pseudoephedrine Sulfate | 194 | 162 |
| 120 mg Pseudoephedrine Sulfate | 97 | 81 |
| Phenylpropanolamine (PPA) | The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only. | |

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APPENDIX H

Guidelines for Emergency Kits in Long Term Care Facilities

A pharmacy may place an emergency kit with controlled substances in a non-DEA registered Long Term Care Facility (LTCF), if the appropriate state agency or regulatory authority specifically approves the placement and promulgates procedures that delineate:

1. The source from which the LTCF may obtain controlled substances for emergency kits and that the source of supply is a DEA-registered hospital/clinic, pharmacy, or practitioner.
2. The security safeguards for each emergency kit stored at the LTCF, including who may have access to the emergency kit, and specific limitation of the type and quantity of controlled substances permitted in the kit.
3. The responsibility for proper control and accountability of the emergency kit within the LTCF, including the requirement that the LTCF and the supplying registrant maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of the controlled substances, and the requirement to take and maintain periodic physical inventories.
4. The emergency medical conditions under which the controlled substances may be administered to LTCF patients, including the requirement that controlled substances be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 C.F.R. §§ 1306.11 and 1306.21.
5. The prohibited activities that if violated could result in state revocation, denial, or suspension of the privilege to supply or possess emergency kits containing controlled substances.

The requirements for emergency kits in LTCFs were published in a *Federal Register* notice on April 9, 1980 (**45 FR 24128**). Pharmacies and LTCFs may wish to consult the notice to ensure compliance with the requirements.

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APPENDIX I

Guidelines for Completing the DEA Form 106

Instructions for completing the DEA Form 106 are provided when filling out either the paper or electronic version of the form. Listed below are additional guidelines:

- Do not use a DEA Form 106 to report an accidental spillage. Save the broken bottles, salvage the product if possible, and contact the local DEA Diversion Field Office (Appendix K) for additional instructions. This type of a loss must be reported on a DEA Form 41, Registrants Inventory of Drugs Surrendered.
- If thefts have occurred due to employee pilferage over a period of time, document on the DEA Form 106 the date of discovery in block 4. Provide estimated beginning and ending dates of the thefts in box 17 with an explanation.
- If there are multiple thefts or losses on the same day (e.g. mail-order pharmacy), report each theft or loss on a separate DEA Form 106.
- Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106. A separate log documenting the discrepancies may be kept at the management's discretion.
- In block 9, enter the number of thefts or losses experienced in the last 24 months, but do not include the current theft or loss being reported. If the current theft or loss was the only theft or loss in the last 24 months, enter 0 (zero).
- In block 12, enter the amount the pharmacy paid for the controlled substances, not the retail value.
- In blocks 14 b & c, if the customer accepted the controlled substance before discovering a loss in transit, identify the supplier and its DEA registration number.
- In block 14f, when explaining how many losses occurred from the same carrier, do not include the current loss.
- The date next to the signature and title on page 2 should be the date the form was completed, signed, and sent to the local DEA Diversion Field Office (Appendix K).
- Document the National Drug Code (NDC) number of the controlled substance, and if the loss was a partial container, document the actual amount of theft or loss within the container.

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Guidelines for Completing the DEA Form 106 (continued)

- If the controlled substance contains hydrocodone, oxycodone or a similar controlled substance and contains acetaminophen, aspirin or ibuprofen, indicate the strength of the non-controlled substance as well as the strength of the controlled substance contained in the product.
- If amending a paper version of a prior DEA Form 106, print **Amended** in the upper front page margin, with the date of the theft.

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APPENDIX J

DEA Registration Specialists in Field Divisions

Registration assistants are available during normal business hours to provide information about new applications, renewals, order forms, or changes to a DEA registration. Addresses and telephone numbers are subject to change. Please refer to the DEA's Diversion website, www.DEAdivision.usdoj.gov, for the most current listing.

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APPENDIX K

DRUG ENFORCEMENT ADMINISTRATION
DIVERSION FIELD OFFICE LOCATIONS

Visit www.DEAdvisors.usdoj.gov for current addresses and telephone numbers.

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APPENDIX L

Internet Resources

DEA's Diversion Control Program Website

www.DEAdiversion.usdoj.gov

DEA Homepage

www.dea.gov

U.S. Government Printing Office

www.gpoaccess.gov/cfr/index.html

Provides access to the C.F.R., Parts 1300 to end, primary source for the Pharmacist's Manual, and the Federal Register which contains proposed and finalized amendments to the C.F.R.

Office of National Drug Control Policy (ONDCP)

www.whitehousedrugpolicy.gov

Food and Drug Administration

www.FDA.gov

HHS & SAMHSA's National Clearinghouse for Alcohol and Drug Information

www.health.org

SAMHSA/CSAT

www.csat.samhsa.gov

Federation of State Medical Boards

www.FSMB.org

National Association of Boards of Pharmacy

www.nabp.net

National Association of State Controlled Substances Authorities

www.nasca.org

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APPENDIX M

Small Business and Agriculture
Regulatory Enforcement Ombudsman

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on DEA enforcement actions, you may contact the Ombudsman at 1-888-REG-FAIR (1-888-734-3247).

Drug Enforcement Administration
Pharmacist's Manual

APPENDIX N

Additional Assistance

This publication is intended to provide guidance and information on the requirements of the CSA and its implementing regulations. If you require additional clarification or assistance, or wish to comment on any matter regarding the DEA's requirements or regulatory activities, please contact your local DEA Diversion Field Office (Appendix K). Every effort will be made to respond promptly to your inquiry.

Plain Language

The Drug Enforcement Administration has made every effort to write this manual in clear, plain language. If you have suggestions as to how to improve the clarity of this manual, please contact us at:

Drug Enforcement Administration
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Springfield, Virginia 22152
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